# 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, 2017**

**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.)** |
| **11045 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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 | ☐ (Do not check if a smaller reporting company) | 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 23, 2017, there were 10,118,659 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 BALANCE SHEETS**
**(In thousands, except par value)**

| | September 30, 2017 (Unaudited) | December 31, 2016 (Note 1) |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 12,079 | $ 44,678 |
| Restricted cash | - | 2,000 |
| Short-term investments | 459 | 8,860 |
| Accounts receivable, net | 10,582 | 11,172 |
| Inventory, net | 29,985 | 21,195 |
| Prepaid and other current assets | 2,887 | 4,187 |
| Total current assets | 55,992 | 92,092 |
| Restricted cash—long-term | 10,000 | - |
| Property and equipment, net | 20,286 | 18,409 |
| Patents, net | 1,539 | 1,784 |
| Other long-term assets | 160 | 107 |
| Total assets | $ 87,977 | $ 112,392 |
| **Liabilities and stockholders' deficit** | | |
| Current liabilities: | | |
| Accounts payable | $ 7,605 | $ 7,513 |
| Accrued expense | 2,536 | 1,629 |
| Employee-related liabilities | 11,413 | 10,183 |
| Deferred revenue | 2,295 | 5,208 |
| Other current liabilities | 5,562 | 6,943 |
| Total current liabilities | 29,411 | 31,476 |
| Notes payable—long-term | 75,596 | 78,960 |
| Deferred rent—long-term | 4,142 | 2,609 |
| Other long-term liabilities | 6,786 | 5,274 |
| Total liabilities | 115,935 | 118,319 |
| Commitments and contingencies (Note 8) | | |
| Stockholders' equity: | | |
| Common stock, $0.001 par value; 100,000 shares authorized as of September 30, 2017 and December 31, 2016, 5,487 and 3,110 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively.(1) | 55 | 31 |
| Additional paid-in capital | 438,194 | 398,623 |
| Accumulated other comprehensive loss | - | (1) |
| Accumulated deficit | (466,207) | (404,580) |
| Total stockholders' deficit | (27,958) | (5,927) |
| Total liabilities and stockholders' deficit | $ 87,977 | $ 112,392 |

*See accompanying notes to unaudited condensed financial statements.*

(1) The issued and outstanding shares of common stock have been restated for all periods presented to reflect the effects of the 1-for-10 reverse stock split, which was effective on October 9, 2017 as described in Note 7.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Sales | $ 27,003 | $ 12,293 | $ 67,306 | $ 55,336 |
| Cost of sales | 15,131 | 13,870 | 40,680 | 41,809 |
| Gross profit (loss) | 11,872 | (1,577) | 26,626 | 13,527 |
| Operating expenses: | | | | |
| Selling, general and administrative | 20,125 | 20,683 | 65,077 | 63,768 |
| Research and development | 4,914 | 6,154 | 14,910 | 14,464 |
| Total operating expenses | 25,039 | 26,837 | 79,987 | 78,232 |
| Operating loss | (13,167) | (28,414) | (53,361) | (64,705) |
| Other income (expense), net: | | | | |
| Interest and other income | 60 | 34 | 179 | 258 |
| Interest and other expense | (2,928) | (1,434) | (8,445) | (4,177) |
| Total other expense, net | (2,868) | (1,400) | (8,266) | (3,919) |
| Net loss | $ (16,035) | $ (29,814) | $ (61,627) | $ (68,624) |
| Other comprehensive loss: | | | | |
| Unrealized gain (loss) on short-term investments | $ - | $ (6) | $ 1 | $ (23) |
| Comprehensive loss | $ (16,035) | $ (29,820) | $ (61,626) | $ (68,647) |
| Net loss per share, basic and diluted[(1)] | $ (3.09) | $ (9.73) | $ (13.79) | $ (22.52) |
| Weighted average shares used to compute basic and diluted net loss per share[(1)] | 5,190 | 3,063 | 4,468 | 3,047 |

*See accompanying notes to unaudited condensed financial statements.*

(1) The issued and outstanding shares of common stock have been restated for all periods presented to reflect the effects of the 1-for-10 reverse stock split, which was effective on October 9, 2017 as described in Note 7.

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2017** | **2016** |
| **Operating activities** | | |
| Net loss | $ (61,627) | $ (68,624) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization expense | 4,737 | 4,017 |
| Interest expense related to amortization of debt discount and debt issuance costs | 1,338 | 194 |
| Provision for allowance for doubtful accounts | 664 | 666 |
| Provision for inventory reserve | 316 | 1,805 |
| Payment in kind interest accrual of notes payable | 1,236 | 675 |
| Amortization of discount on short-term investments | (16) | (59) |
| Stock-based compensation expense | 10,502 | 8,733 |
| Other | 69 | (37) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | (73) | 5,191 |
| Inventory, net | (9,038) | (7,110) |
| Prepaid and other current assets | 1,133 | (1,408) |
| Other long-term assets | (53) | (8) |
| Accounts payable | 522 | 291 |
| Accrued expense | 907 | (144) |
| Employee-related liabilities | 797 | (1,225) |
| Deferred revenue | (4,137) | 8,528 |
| Other current liabilities | (601) | 1,348 |
| Deferred rent | (425) | (566) |
| Other long-term liabilities | (746) | 142 |
| Net cash used in operating activities | (54,495) | (47,591) |
| **Investing activities** | | |
| Purchase of short-term investments | — | (25,890) |
| Proceeds from sales and maturities of short-term investments | 8,500 | 37,950 |
| Purchase of property and equipment | (4,299) | (6,187) |
| Net cash provided by investing activities | 4,201 | 5,873 |
| **Financing activities** | | |
| Issuance of notes payable, net of issuance costs | — | 14,994 |
| Restricted cash in connection with notes payable | (8,000) | — |
| Proceeds from public offering, net of offering costs | 25,125 | — |
| Proceeds from issuance of common stock | 570 | 1,592 |
| Net cash provided by financing activities | 17,695 | 16,586 |
| Net decrease in cash and cash equivalents | (32,599) | (25,132) |
| Cash and cash equivalents at beginning of period | 44,678 | 43,088 |
| Cash and cash equivalents at end of period | $ 12,079 | $ 17,956 |
| **Supplemental disclosures of cash flow information** | | |
| Interest paid | $ 5,871 | $ 3,205 |
| **Supplemental schedule of noncash investing and financing activities** | | |
| Lease incentive - lessor-paid tenant improvements | $ 3,037 | $ — |
| Debt discount included in other long-term liabilities | $ 4,116 | $ 454 |
| Common stock warrants issued in connection with term loan | $ 3,331 | $ — |
| Property and equipment included in accounts payable | $ 72 | $ 802 |

*See accompanying notes to unaudited condensed 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 in the United States that are designed to address large and differentiated needs of the insulin-dependent diabetes market. The Company's pump products currently include:

- the t:slim X2 Insulin Delivery System, or t:slim X2, the next-generation flagship product that is updatable and designed to display Dexcom G5 continuous glucose monitoring, or CGM, sensor information directly on the pump Home Screen; and

- the t:flex Insulin Delivery System, or t:flex, for people with greater insulin needs.

The Company began commercial sales of its first product, t:slim, in August 2012. During 2015, the Company commenced commercial sales of two additional insulin pumps: t:flex in May 2015 and t:slim G4 in September 2015. In October 2016, the Company commenced commercial sales of t:slim X2 and discontinued new sales of t:slim. In August 2017, the Company commenced commercial sales of t:slim X2 with Dexcom G5 Mobile CGM integration, or t:slim X2 with G5, and discontinued new sales of t:slim G4. The Company will continue to provide ongoing service and support to existing t:slim and t:slim G4 customers.

In July 2016, the Company received clearance from the U.S. Food and Drug Administration ("FDA") to begin offering the Tandem Device Updater, a Mac and PC-compatible tool for the remote update of Tandem insulin pump software.

In July 2016, the Company also announced and launched a Technology Upgrade Program that provided eligible t:slim and t:slim G4 customers a path to obtain t:slim X2, or, as of August 2017, t:slim X2 with G5. Participating customers had the right to exchange their original t:slim and t:slim G4 for a t:slim X2 or t:slim X2 with G5, under a variable pricing structure. The Technology Upgrade Program expired on September 30, 2017.

In September 2017, the Company commenced commercial sales of products using the t:lock™ Connector, or t:lock, which replaces the standard Luer-lok connector that historically joined an infusion set to the cartridge. t:lock incorporates a smaller inner cavity than the Luer-lok connector, which reduces the amount of insulin used in the process and reduces the time required to fill the infusion set tubing.

Effective December 31, 2016, the Company adopted FASB Accounting Standard Codification ("ASC") Topic 205-40, Presentation of Financial Statements – Going Concern, which requires management to evaluate whether there are relevant conditions and events that, in the aggregate, raise substantial doubt about the entity's ability to continue as a going concern and to meet its obligations as they become due within one year after the date the financial statements are issued.

The financial statements included in this Quarterly Report on form 10-Q for the three and nine months ended September 30, 2017 (the "Quarterly Report") have been prepared on a basis that assumes the Company will continue as a going concern, and do not include any adjustments that may result from the outcome of this uncertainty. This basis of accounting contemplates the recovery of the Company's assets and the satisfaction of the Company's liabilities and commitments in the normal course of business and does not include any adjustments to reflect the possible future effects of the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

The Company has incurred operating losses since its inception and, as reflected in the accompanying financial statements, the Company has an accumulated deficit of $466.2 million as of September 30, 2017, which reflects a net loss of $61.6 million for the nine months ended September 30, 2017. The Company had cash and cash equivalents and short-term investments of $22.5 million at September 30, 2017, including $10.0 million of restricted cash as required by the Company's term loan agreement (as amended, the "Term Loan Agreement") with Capital Royalty Partners II, L.P. and its affiliate funds ("Capital Royalty Partners"). The Company used $54.5 million in cash from operations in the nine months ended September 30, 2017. The Company concluded that, at the date the financial statements in this Quarterly Report were issued, it did not have sufficient cash to fund its operations for the next twelve months without additional financing and, therefore, there was substantial doubt about its ability to continue as a going concern within one year after the date the financial statements were issued.

On October 9, 2017, the Company effected a 1-for-10 reverse stock split of its issued and outstanding shares of common stock. The par value per share and the authorized number of shares of common stock and preferred stock were not adjusted as a result of the reverse stock split. All common stock share and per-share amounts for all periods presented in these condensed financial statements have been adjusted to reflect the reverse stock split. The number of authorized shares of common stock remains at 100 million shares.

The Company completed a registered public offering on October 17, 2017, or the October Financing, which resulted in gross proceeds to the Company of $16.2 million, before deducting underwriting discounts and commissions and other offering expenses (see Note 9 “Subsequent Events”). As part of the October Financing, the Company issued 4,630,000 shares of common stock, Series A warrants to purchase 4,630,000 shares of common stock and Series B warrants to purchase 4,630,000 shares of common stock, at a public offering price of $3.50 per share and accompanying warrants. The Series A warrants have an exercise price of $3.50 per share, are immediately exercisable, and will expire on the 5-year anniversary of the date of issuance. The Series B warrants have an exercise price of $3.50 per share, are immediately exercisable, and will expire on the 6-month anniversary of the date of issuance. Each series of warrants, if exercised by all holders in full, may result in additional gross proceeds of $16.2 million to the Company. As a result of the completion of the financing, the Company has satisfied the equity financing covenant in the Term Loan Agreement (see Note 6, “Term Loan Agreement”), although it remains subject to additional covenants.

The Company believes it will be necessary to raise additional funding. The Company intends to seek additional capital from public or private offerings of its capital stock or it may elect to borrow additional amounts under new debt financing arrangements or from other sources. If the Company issues equity or convertible debt securities to raise additional funding, its existing stockholders may experience dilution, it may incur significant financing costs, and the new equity or convertible debt securities may have rights, preferences and privileges senior to those of its existing stockholders. If the Company issues debt securities to raise additional funding, it would incur additional debt service obligations, it could become subject to additional restrictions limiting its ability to operate its business, and it may be required to further encumber its assets. The Company’s ability to continue as a going concern, meet its minimum liquidity requirements, satisfy the covenants under the Term Loan Agreement, and execute its business strategy is dependent on its ability to raise significant additional capital, of which there can be no assurance. If the Company cannot generate sufficient revenues from the sale of its products or secure additional financing on acceptable terms, it may be forced to significantly alter its business strategy, substantially curtail or modify its current operations, or cease operations altogether.

***Basis of Presentation***

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

Interim financial results are not necessarily indicative of results anticipated for the full year or any other period(s). These unaudited condensed 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, 2016 (“Annual Report”), from which the balance sheet information herein was derived. These unaudited condensed financial statements exclude disclosures required by U.S. GAAP for complete financial statements.

**2. Summary of Significant Accounting Policies**

There have been no significant changes in our significant accounting policies during the nine months ended September 30, 2017, as compared with those disclosed in the Annual Report.

***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.

***Restricted Cash***

The Company recorded $10.0 million and $2.0 million of restricted cash as of September 30, 2017 and December 31, 2016, respectively, for the minimum cash balance requirement in connection with the Term Loan Agreement (see Note 6, “Term Loan Agreement”).

***Accounts Receivable***

The Company grants credit to various customers in the normal 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, specific review of outstanding invoices, and various additional assumptions and estimates that are believed to be reasonable under the circumstances. Uncollectible accounts are written off against the allowance after appropriate collection efforts have been exhausted and when it is deemed that a balance is uncollectible.

***Fair Value of Financial Instruments***

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, accrued expenses, and employee-related liabilities are reasonable estimates of their fair values because of the short-term nature of these assets and liabilities. Short-term investments are carried at fair value. Based on the borrowing rates currently available for loans with similar terms, the Company believes that the fair value of its long-term notes payable approximates its carrying value.

Certain trade-in rights offered by the Company pursuant to the Technology Upgrade Program to certain eligible customers, have been determined to be guarantees under applicable accounting guidance. The Company recorded a liability for the estimated fair value of the guarantees at their inception. The Program expired on September 30, 2017, at which time the remaining guarantee liabilities of $1.1 were recognized as sales. For further details regarding these guarantees, see the information included under the heading “Revenue Recognition” within this Note 2, as well as the information in Note 5, “Fair Value Measurements.”

***Revenue Recognition***

Revenue is generated primarily from sales in the United States 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.

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred and title passed, the price is fixed or determinable, and collectability is reasonably assured.

*Trade-In Rights*

The Company launched a Technology Upgrade Program in 2016, which expired September 30, 2017. The trade-in rights associated with the Program were accounted for as guarantees or rights to return based on specific factors and circumstances, including the period of time the trade-in rights were exercisable, the likelihood that the trade-in rights would be exercised, and the amount of the specified-price trade-in value.

The Company determined that trade-in rights for t:slim G4 Pump customers were generally guarantees. The Company accounted for the guarantees under applicable accounting standards, which require a guarantor to recognize, at the inception of the guarantees, a liability for the estimated fair value of the obligation undertaken in issuing the guarantees. Subsequently, the initial liability recognized for the guarantees was reduced as the Company was released from the risk under the guarantees, which was when the trade-in right was exercised or the right expired. The guarantees were accounted for as an element of a multiple element arrangement. The estimated fair value of the guarantees was based on various economic and customer behavioral assumptions, including the probability that a trade-in right would be exercised, the specified trade-in amount, the expected fair value of the used t:slim G4 Pump at trade-in and the expected sales price of a t:slim X2 Pump. Upon expiration of the Program at September 30, 2017, the remaining guarantee liabilities of $1.1 were recognized as sales compared to $1.2 million recorded as guarantee liabilities in other current liabilities on the accompanying balance sheets, as of September 30, 2017 and December 31, 2016, respectively.

The Company determined that t:slim Pump trade-in rights were in-substance rights to return products. Such rights to return were accounted for pursuant to the right of return accounting guidance. As the Company did not have sufficient history to reasonably estimate returns associated with trade-in rights, all eligible t:slim Pump sales between July 2016 and October 2016, which is when the Company discontinued new shipments of t:slim, were recorded as deferred revenue until the trade-in right was exercised or the right expired. Despite expiration of the Program at September 30, 2017, the Company recorded $0.2 million for upgrades requested but not yet fulfilled compared to $3.2 million as a trade-in rights reserve in deferred revenue on the accompanying balance sheets, as of September 30, 2017 and December 31, 2016, respectively.

*Revenue Recognition for Arrangements with Multiple Deliverables*

The Company considers the deliverables in its product offering as separate units of accounting and recognizes deliverables as revenue upon delivery only if (i) the deliverable has standalone value and (ii) the arrangement includes a general right of return relative to the delivered item(s) and delivery or performance of the undelivered item(s) is probable and substantially controlled by the Company. The Company allocates consideration to the separate units of accounting, unless the undelivered elements were deemed perfunctory and inconsequential. The amount of the determined guarantee fair value is allocated in full to the guarantee and the remaining allocable consideration is allocated to other separate units of accounting using the relative selling price method, in which allocation of consideration is based on vendor-specific objective evidence ("VSOE") if available, third-party evidence ("TPE"), or if VSOE and TPE are not available, management's best estimate of a standalone selling price ("ESP") for the undelivered elements.

The Company offers a cloud-based data management application, t:connect, which is made available to customers upon purchase of any of its insulin pumps. In July 2016, the Company received clearance from the FDA to begin offering the Tandem Device Updater, a Mac and PC-compatible tool for the remote update of Tandem insulin pump software. Utilizing Tandem Device Updater, the Company may from time to time provide future unspecified software upgrades to the insulin pump's essential software. The t:connect service and the embedded right included with qualifying insulin pumps to receive, on a when-and-if-available basis, future unspecified software upgrades relating to the product's essential software are deemed undelivered elements at the time of the insulin pump sale. Because the Company has neither VSOE nor TPE for these deliverables, the allocation of revenue is based on the Company's ESP. The Company establishes its ESP based on the estimated cost to provide such services, including consideration for a reasonable profit margin, which is then corroborated by comparable market data. The Company allocates fair value based on management's ESP to these elements at the time of sale and recognizes the revenue over a four-year period, which is the hosting period for t:connect and the period that software upgrades are expected to be provided. At September 30, 2017 and December 31, 2016, $1.8 million and $1.6 million, respectively, were recorded as deferred revenue for these undelivered elements. All other undelivered elements at the time of sale are deemed inconsequential or perfunctory.

*Product Returns*

The Company offers a 30-day right of return to its customers from the date of shipment of any of its insulin pumps, provided a physician's confirmation of the medical reason for the return is received. Estimated allowances for sales returns are based on historical returned quantities as compared to pump shipments in those same periods of return. The return rate is then applied to the sales of the current period to establish a reserve at the end of the period. The return rates used in the reserve are adjusted for known or expected changes in the marketplace when appropriate. The allowance for product returns is recorded as a reduction of revenue and accounts receivable in the period in which the related sale is recorded. The amount recorded on the Company's balance sheets for product return allowance was $0.2 million and $0.2 million at September 30, 2017 and December 31, 2016, respectively. Actual product returns have not differed materially from estimated amounts reserved in the accompanying condensed 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 warranty reserve.

At September 30, 2017 and December 31, 2016, the warranty reserve was $4.8 million and $5.7 million, respectively. The following table provides a reconciliation of the change in product warranty liabilities from December 31, 2016 through September 30, 2017 (in thousands):

| | | |
|---|---|---|
| Balance at December 31, 2016 | $ | 5,690 |
| Provision for warranties issued during the period | | 4,110 |
| Settlements made during the period | | (5,240) |
| Increases in warranty estimates | | 190 |
| Balance at September 30, 2017 | $ | 4,750 |
| | | |
| Current portion | $ | 2,080 |
| Non-current portion | | 2,670 |
| Total | $ | 4,750 |

***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 net loss per share is calculated by dividing the net loss by the sum of the weighted average number of common shares that were outstanding for the period and the weighted-average number of dilutive common share equivalents outstanding for the period determined using the treasury stock method. Dilutive common share equivalents are comprised of warrants, options outstanding under the Company's equity incentive plans, and shares subject to issuance pursuant to the ESPP. 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, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Common stock warrants | - | 99 | - | 99 |
| Common stock options | 8 | 293 | 3 | 262 |
| ESPP | - | 13 | - | 7 |
| | 8 | 405 | 3 | 368 |

***Recent Accounting Pronouncements***

In August 2016, the Financial Accounting Standards Board ("FASB") issued new guidance that clarifies how entities should classify certain cash receipts and cash payments on the statement of cash flows. The guidance also clarifies how the predominance principle should be applied when cash receipts and cash payments have aspects of more than one class of cash flows. The guidance is effective for public companies for fiscal years beginning after December 15, 2017, and interim periods within those years. The Company does not believe the adoption of the standard will have a material impact on the Company's statement of cash flow.

In June 2016, FASB issued a new credit loss standard that changes the impairment model for most financial assets and certain other instruments. The standard is effective for public business entities for annual periods beginning after December 15, 2019, and interim periods within those years. Early adoption is permitted for all entities for annual periods beginning after December 15, 2018, and interim periods within those years. The Company is in the process of assessing the impact of the adoption of the standard on its financial statements.

In March 2016, FASB issued ASU 2016-09, Compensation - Stock Compensation (Topic 718) ("ASU 2016-09"), which is intended to simplify several areas of accounting for share-based payment arrangements. The amendments in this update cover such areas as the recognition of excess tax benefits and deficiencies, the classification of those excess benefits on the statement of cash flows, an accounting policy election for forfeitures, the amount an employer can withhold to cover income taxes and still qualify for equity classification and the classification of those taxes paid on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, and interim periods within those annual periods. The Company adopted this standard in the first quarter of 2017. The Company had excess tax benefits for which a benefit could not previously be recognized of approximately $656,000 as of December 31, 2016. Upon adoption, the balance of the unrecognized excess tax benefits was reversed with the impact recorded to (accumulated deficit) retained earnings, including any change to the valuation allowance as a result of the adoption. Due to the full valuation allowance on the U.S. deferred tax assets as of December 31, 2016, there was no impact to the financial statements as a result of this adoption.

In February 2016, FASB issued final guidance for lease accounting. The new guidance requires lessees to put most leases on their balance sheet but to recognize expenses on their income statement in a manner similar to current accounting principles. The new guidance also eliminates the current real estate-specific provisions for all entities. The standard is effective for public companies for annual periods beginning after December 15, 2018, and interim periods within those years. Early adoption is permitted for all entities. The Company is in the process of assessing the impact of the adoption of the standard on its financial statements.

In May 2014, FASB and the International Accounting Standards Board issued a comprehensive new revenue recognition standard ("Revenue from Contracts with Customers Standard") that will supersede existing revenue guidance under U.S. GAAP and International Financial Reporting Standards. The Revenue from Contracts with Customers Standard's core principle is that a company will recognize 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. In doing so, companies will need to use more judgment and make more estimates than under current guidance. The Revenue from Contracts with Customers Standard will be effective for the Company beginning in its first quarter of 2018, and early adoption is permitted.

Subsequently, FASB issued the following standards related to Revenue from Contracts with Customers Standard: Principal versus Agent Considerations; Identifying Performance Obligations and Licensing; and Narrow-Scope Improvements and Practical Expedients (collectively, the "new revenue standards"). The new revenue standards may be applied retrospectively to each prior period presented (full retrospective method) or retrospectively with the cumulative effect recognized as of the date of adoption (the modified retrospective method). The Company currently expects to adopt the new revenue standards in the first quarter of 2018 utilizing the modified retrospective method. The Company currently believes that the adoption will not have a material impact on the recognition of revenues for the sale of its products through third-party distributors and insurance payors with whom it has contractual arrangements, which generally comprise approximately 99% of its sales. Additionally, the Company has given consideration to the accounting for warranty and commissions and does not anticipate a material change to its current method of expense recognition. As of September 30, 2017, the Company has not determined the full impact the adoption of the new revenue standard may have on its reported revenue or results of operations.

**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 at September 30, 2017 and December 31, 2016 (in thousands):

| At September 30, 2017 | Maturity (in years) | Amortized Cost | Unrealized Gain | Unrealized Loss | Estimated Fair Value |
|---|---|---|---|---|---|
| Trading securities: | | | | | |
| Mutual funds held for nonqualified deferred compensation plan participants | | $ 416 | $ 43 | $ — | $ 459 |
| **Total** | | $ 416 | $ 43 | $ — | $ 459 |

| At December 31, 2016 | Maturity (in years) | Amortized Cost | Unrealized Gain | Unrealized Loss | Estimated Fair Value |
|---|---|---|---|---|---|
| Available-for-sale investment securities: | | | | | |
| Commercial paper | Less than 1 | $ 8,483 | $ 1 | $ (2) | $ 8,482 |
| Trading securities: | | | | | |
| Mutual funds held for nonqualified deferred compensation plan participants | | $ 354 | $ 26 | $ (2) | $ 378 |
| **Total** | | $ 8,837 | $ 27 | $ (4) | $ 8,860 |

**4. Inventory**

Inventory consisted of the following at September 30, 2017 and December 31, 2016 (in thousands):

| | September 30, 2017 | December 31, 2016 |
|---|---|---|
| Raw materials | $ 10,138 | $ 9,375 |
| Work in process | 5,497 | 4,395 |
| Finished goods | 14,350 | 7,425 |
| **Total** | $ 29,985 | $ 21,195 |

The increase in inventory at September 30, 2017 as compared to December 31, 2016 is primarily due to an increase in infusion set finished goods in connection with the commercial launch of the t:lock infusion set.

**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, 2017 and December 31, 2016, 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, 2017 | | |
|---|---|---|---|---|
| | | (Level 1) | (Level 2) | (Level 3) |
| **Assets** | | | | |
| Cash equivalents (1) | $ 16,527 | $ 16,527 | $ — | $ — |
| Mutual funds held for nonqualified deferred compensation plan participants (2) | 459 | 459 | — | — |
| Total assets | $ 16,986 | $ 16,986 | $ — | $ — |
| **Liabilities** | | | | |
| Deferred compensation (2) | $ 459 | $ 459 | $ — | $ — |
| Total liabilities | $ 459 | $ 459 | $ — | $ — |

| | | Fair Value Measurements at December 31, 2016 | | |
|---|---|---|---|---|
| | | (Level 1) | (Level 2) | (Level 3) |
| **Assets** | | | | |
| Cash equivalents (1) | $ 39,941 | $ 39,941 | $ — | $ — |
| Commercial paper | 8,482 | — | 8,482 | — |
| Mutual funds held for nonqualified deferred compensation plan participants (2) | 378 | 378 | — | — |
| Total assets | $ 48,801 | $ 40,319 | $ 8,482 | $ — |
| **Liabilities** | | | | |
| Deferred compensation (2) | $ 378 | $ 378 | $ — | $ — |
| Total liabilities | $ 378 | $ 378 | $ — | $ — |

(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 is classified as restricted cash – long-term at September 30, 2017.

(2) The deferred compensation plan is 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 are 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'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, 2017.

The Company recorded $1.2 million as guarantee liabilities in other current liabilities on the accompanying condensed balance sheet at December 31, 2016. There were no guarantee liabilities at September 30, 2017. Guarantees were recorded as a reduction of revenue in the statement of operations and other comprehensive loss. Guarantees are not measured at fair value on a recurring basis, and therefore are not included in the tables above. Guarantees are classified within Level 3 of the fair value hierarchy. The estimated fair value of the guarantees is based on various economic and customer behavioral assumptions, including the probability that a trade-in right will be exercised, the specified trade-in amount, the expected fair value of the used t:slim G4 Pump at trade-in and the expected sales price of t:slim X2 (see Note 2, "Summary of Significant Accounting Policies – Revenue Recognition"). Changes in the probability that a trade-in right will be exercised have the most significant impact on the estimate of the fair value of the liabilities.

In connection with the Term Loan Agreement, on March 7, 2017, the Company issued ten-year warrants to purchase 193,788 shares of the Company's common stock at an exercise price of $23.50 per share (the "Capital Royalty Warrant"). The Company used the Black-Scholes option-pricing model to calculate the value of the Capital Royalty Warrant of approximately $3.3 million. The Capital Royalty Warrant was recorded as debt discount and stockholders' equity, as the warrants met the definition of an equity instrument. 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.

**6. Term Loan Agreement**

The Company had $82.3 million and $81.1 million of aggregate borrowings outstanding under the Term Loan Agreement, at September 30, 2017 and December 31, 2016, respectively.

Under the Term Loan Agreement, interest is 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 are due quarterly on March 31, June 30, September 30 and December 31 of each year of the interest-only payment period, which ends on December 31, 2019. The principal balance is due in full at the end of the term of the loan, which is 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. Beginning October 1, 2015, 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, $2.3 million was added to the principal of the loan since October 1, 2015, which the Company refers to as PIK Loans.

The term loan is collateralized by all assets of the Company. The principal financial covenants require that the Company attain minimum annual revenues of $80.0 million in 2017 and $95.0 million each year thereafter until the Maturity Date.

Pursuant to Amendment No. 3 to Term Loan Agreement (the "Third Amendment"), the Company agreed to pay, on the earlier of (i) the Maturity Date, (ii) the date that the loan under the Term Loan Agreement becomes due, and (iii) the date on which the Company makes a voluntary pre-payment of the loan, a financing fee equal to 3.0% of the sum of (x) the aggregate amount drawn under the Third Amendment, which is $50.0 million, and (y) any PIK Loans issued in relation to the Third Amendment (collectively, the "Back End Financing Fee").

The audit report of the Company's independent registered public accounting firm contained in the Annual Report included an explanatory paragraph that describes conditions that raise substantial doubt about the Company's ability to continue as a going concern. This explanatory paragraph constituted a potential event of default under the Term Loan Agreement. On March 7, 2017, the Company entered into Waiver and Amendment No. 4 to the Term Loan Agreement (the "Fourth Amendment"), which included a limited waiver of the potential event of default that could have resulted from the explanatory paragraph. In consideration for the waiver, the Company agreed to: (i) issue the Capital Royalty Warrant, (ii) increase its restricted cash balance from $2.0 million to $10.0 million, (iii) provide Capital Royalty Partners the same information it makes available to its board of directors, subject to limited exceptions, and (iv) not incur additional third party indebtedness secured solely by accounts receivable, inventory and cash. In addition, the Fourth Amendment includes a covenant requiring the Company to complete financings in which its gross proceeds from the sale of equity securities is at least $30.0 million, no later than January 15, 2018. Furthermore, the Company agreed to increase the Back End Financing Fee to 5.0% of the entire aggregate principal amount of borrowings outstanding, including total PIK Loans issued. The Back End Financing Fee is payable at maturity of the Company's loans and on the principal amount of any loans for which it makes an optional prepayment, and may be payable in connection with certain asset sales or a change of control.

As of September 30, 2017 and December 31, 2016, respectively, the Company had accrued $4.1 million and $1.5 million for the Back End Financing Fee in other long-term liabilities and as contra-debt in notes payable-long-term on the accompanying condensed balance sheets.

The Company evaluated execution of the Fourth Amendment as a modification for accounting purposes and concluded that it did not constitute a modification because the present value of the future cash flows under the Fourth Amendment did not exceed the present value of the future cash flows under the previous terms by more than 10%. The Back End Financing Fee, the value of the Capital Royalty Warrant, and the remaining balance of debt issuance costs and debt discount of the loan are amortized to interest expense over the remaining term of the Term Loan Agreement using the effective interest method.

**7. Stockholders' Equity**

***Public Offering***

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.

***At The Market (ATM) Program***

In July 2017, the Company entered into an Equity Distribution Agreement implementing an ATM program for aggregate gross proceeds up to $15.0 million. During the three months ended September 30, 2017, the Company sold 464,108 shares of common stock under the ATM program at prices ranging from $5.64 to $10.54. The gross proceeds to the Company from these sales were $4.3 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 at September 30, 2017 (in thousands):

| | |
|---|---|
| Shares underlying outstanding warrants | 293 |
| Shares underlying outstanding stock options | 933 |
| Shares authorized for future equity award grants | 39 |
| Shares authorized for issuance as ESPP awards | — |
| | 1,265 |

The Company issued 24,408 shares of its common stock upon the exercise of stock options during the nine months ended September 30, 2017, and issued 14,897 shares of its common stock upon the exercise of stock options during the year ended December 31, 2016.

The ESPP enables eligible employees to purchase shares of the Company's common stock using their after tax payroll deductions, subject to certain conditions. The ESPP consists of a two-year offering period with four six-month purchase periods which begin in May and November of each year. There were 38,929 shares of the Company's common stock purchased under the ESPP during the nine months ended September 30, 2017, and 69,502 shares of the Company's common stock purchased under the ESPP during the year ended December 31, 2016.

The Company announced the suspension of the ESPP as of May 16, 2017 due to a lack of available shares. The suspension was accounted for as a cancellation of an award with no consideration. The previously unrecognized compensation cost as of the suspension date of $2.4 million was fully expensed during the second quarter of 2017.

***Stock-Based Compensation***

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

| | Stock Option | | | |
|---|---|---|---|---|
| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
| | 2017 | 2016 | 2017 | 2016 |
| Weighted average grant date fair value (per share) | $ 3.00 | $ 35.00 | $ 5.10 | $ 37.80 |
| Risk-free interest rate | 2.0% | 1.3% | 1.9% | 1.4% |
| Expected dividend yield | 0.0% | 0.0% | 0.0% | 0.0% |
| Expected volatility | 60.3% | 56.1% | 60.0% | 55.5% |
| Expected term (in years) | 6.1 | 6.1 | 6.1 | 6.1 |

| | ESPP | |
|---|---|---|
| | Nine Months Ended September 30, | |
| | 2017(1) | 2016 |
| Weighted average grant date fair value (per share) | N/A | $ 26.90 |
| Risk-free interest rate | N/A | 0.6% |
| Expected dividend yield | N/A | 0.0% |
| Expected volatility | N/A | 56.9% |
| Expected term (in years) | N/A | 1.3 |

(1) There were no grants made pursuant to the ESPP during the three and 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, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Cost of sales | $ 264 | $ 267 | $ 1,022 | $ 776 |
| Selling, general & administrative | 1,961 | 2,320 | 8,423 | 6,992 |
| Research and development | 167 | 318 | 1,057 | 965 |
| Total | $ 2,392 | $ 2,905 | $ 10,502 | $ 8,733 |

The total stock-based compensation expense capitalized as part of the cost of inventory was $0.3 million and $0.2 million at September 30, 2017 and December 31, 2016, respectively.

**8. Commitments and Contingencies**

From time to time, the Company may be subject to legal proceedings, regulatory encounters or other matters 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 assesses, on a regular basis, the probability and 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 loss has been incurred, and that the amount or range of the loss can be reasonably estimated. Because of the uncertainties related to the occurrence, amount, and range of loss on any pending actions, the Company is currently unable to predict their ultimate outcome, and, with respect to any pending litigation 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 unfavorable outcome. At September 30, 2017 and December 31, 2016, there were no legal proceedings, regulatory encounters or other matters for which the negative outcome was considered probable or for which the amount or range of loss was estimable.

**9. Subsequent Event**

On October 9, 2017, the Company effected a 1-for-10 reverse stock split of its issued and outstanding shares of common stock. The par value per share and the authorized number of shares of common stock and preferred stock were not adjusted as a result of the reverse stock split. All common stock share and per-share amounts for all periods presented in these condensed financial statements have been adjusted to reflect the reverse stock split. The number of authorized shares of common stock remains at 100 million shares.

On October 17, 2017, the Company completed a registered public offering of 4,630,000 shares of its common stock, Series A warrants to purchase up to 4,630,000 shares of its common stock and Series B warrants to purchase up to 4,630,000 shares of its common stock, at a public offering price of $3.50 per share and accompanying warrants. The gross proceeds to the Company from the offering were approximately $16.2 million, before deducting underwriting discounts and commissions and other offering expenses payable by the Company. The Series A warrants have an exercise price of $3.50 per share, are immediately exercisable, and will expire on the 5-year anniversary of the date of issuance. The Series B warrants have an exercise price of $3.50 per share, are immediately exercisable, and will expire on the 6-month anniversary of the date of issuance. As a result of the completion of the financing, the Company has satisfied the equity financing covenant in the Term Loan Agreement, although it remains subject to additional covenants.

**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 period ended September 30, 2017, or this Quarterly Report.*

*This Quarterly Report contains forward-looking statements within the meaning of the federal securities laws. 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 financial condition (including our ability to continue as a going concern), 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, competitive environment, and the application of accounting guidance. We caution you that the foregoing list may not include all of the forward-looking statements made in this Quarterly Report.*

*Our forward-looking statements are based on our management's current assumptions and expectations about future events and trends, which affect or may affect our business, strategy, operations or financial performance. Although we believe that these forward-looking statements are based upon reasonable assumptions, they are subject to numerous known and unknown risks and uncertainties and are made in light of information currently available to us. Our actual financial condition and results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below in the section entitled "Risk Factors" in Part II, Item 1A, and elsewhere in this Quarterly Report. You should read this Quarterly Report with the understanding that our actual future financial condition and results may be materially different and worse from 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 that our competitive advantage is rooted in our unique consumer-focused approach and proprietary technology platform. This allows us to deliver innovative hardware and software solutions to meet the various needs and preferences of people with diabetes and their healthcare providers. We manufacture and sell insulin pump products in the United States that are designed to address large and differentiated segments of the insulin-dependent diabetes market. Our insulin pump products include:

- the t:slim X2 Insulin Delivery System, or t:slim X2, our next-generation flagship product that is updatable and designed to display Dexcom G5 continuous glucose monitoring, or CGM, sensor information directly on the pump Home Screen; and

- the t:flex Insulin Delivery System, or t:flex, for people with greater insulin needs.

We have shipped more than 60,000 insulin pumps since our initial launch in August 2012, of which nearly 56,000 pumps have been shipped within the four years ended September 30, 2017. For the past three consecutive years, our company has been ranked #1 by insulin pump users in the United States for customer support in an independent survey by dQ&A, a leading diabetes research firm.

We have successfully launched five insulin pump products, beginning with the commercialization of our first pump, the t:slim Insulin Delivery System, or t:slim, in August 2012. During 2015, we commenced commercial sales of two additional insulin pumps: t:flex and the t:slim G4 Insulin Delivery System, or t:slim G4, the first continuous glucose monitoring, or CGM, enabled pump with touchscreen simplicity. In October 2016, we commenced commercial sales of t:slim X2 and discontinued new sales of t:slim. In August 2017, we commenced commercial sales of t:slim X2 with Dexcom G5 Mobile CGM integration and discontinued new sales of t:slim G4.

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. Remote updatability for insulin pump software is a unique feature not available in competitive pump offerings, meaning the Tandem Device Updater provides our customers access to new and enhanced features faster than the industry has been able to in the past. Its first cleared use by the U.S. Food and Drug Administration, or FDA, was to update t:slim Pumps purchased before April 2015 to the latest software. In August 2017, we received FDA approval to permit t:slim X2 customers to update their pumps' software to allow integration with the Dexcom G5 Mobile CGM system. We are currently offering this update free of charge to our 12,000 customers that purchased a t:slim X2 prior to us receiving FDA approval for G5 integration. As of September 30, 2017, approximately one third of these customers have elected to update their pump. Of the t:slim X2 Pump users who have updated their pump's software, more than 85% indicated they were satisfied or extremely satisfied with the update process. In the future, the Tandem Device Updater has the potential to enable users to add other new features and functionality to their pumps, such as automated insulin delivery, or AID, algorithms, independent of the typical four-year insurance pump replacement cycle.

In September 2017, we commenced commercial sales of products using the t:lock™ Connector, or t:lock, which replaces the standard Luer-lok connector that historically joined an infusion set to our cartridge. t:lock incorporates a smaller inner cavity than the Luer-lok connector, which reduces the amount of insulin used in the process and reduces the time required to fill the infusion set tubing.

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, allowing users to successfully operate our devices 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 pumping technology allows us to design the slimmest and smallest durable insulin pumps on the market, without sacrificing insulin capacity. Our insulin pump 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, a vivid color touchscreen and, with the t:slim X2, it also 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 insulin pump 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.

We have rapidly increased sales since our commercial launch by expanding our sales, clinical and marketing infrastructure, by developing, commercializing and marketing multiple differentiated products that utilize our technology platform and consumer-focused approach, and by providing strong customer support. In our research, approximately 86% of healthcare providers surveyed believe that providing great customer support is the most important company attribute. 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 well positioned to address consumers' needs and preferences with our current products and products under development and by offering customers a pathway to our future innovations through the Tandem Device Updater as they are approved by the FDA.

In July 2017, we announced plans to begin commercialization of t:slim X2 outside the United States in select geographies during 2018. Unlike our approach domestically, we currently plan to partner with distributors who will carry out the selling efforts, as well as the service and support of customers in geographies outside the United States.

***Products under Development***

Our products under development support our strategy of focusing on both consumer and clinical needs. We intend to leverage our consumer-focused approach and proprietary technology platform to continue to develop products that have the features and functionality that will allow us to target people in different segments of the insulin-dependent diabetes market. Our current pump products under development include:

- t:slim X2 with PLGS – Our first generation AID system is expected to include a predictive low glucose suspend, or PLGS, algorithm that utilizes Dexcom G5 sensor values. During 2016, we completed a feasibility study of our PLGS algorithm. The data from this feasibility study was used in an IDE submission for a pivotal study, which was approved by the FDA in May 2017. We commenced a pivotal study for our t:slim X2 with PLGS in the third quarter of 2017 and anticipate that it will conclude by the end of 2017. Once reports from the clinical trial sites are finalized, we intend to use the results in a PMA submission with the FDA. Based on this timing, and subject to future FDA approval, our goal is to launch the product in the summer of 2018.

- t:slim X2 with TypeZero – 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 sensor. With TypeZero's technology, our product is intended to both increase and decrease basal insulin based on a person's predicted blood glucose levels, as well as deliver automated correction boluses. In November 2016, we announced that we are working with Dexcom and TypeZero on the integration of our technologies into the National Institute of Health funded International Diabetes Closed Loop Trial, or IDCL Trial. We anticipate that a portion of the trial will utilize a t:slim X2 integrated with TypeZero's inControl AID algorithms that is designed to automatically adjust a person's insulin based on information from a Dexcom G6 sensor. We intend to use the results from this portion of the trial in a PMA submission with the FDA. Subject to both the timely completion of a successful IDCL Trial and future FDA approval, our goal is to launch this product in the first half of 2019.

- t:sport Insulin Delivery System – This product is expected to be half the size of t:slim and is being designed for people who seek even greater discretion and flexibility with the use of their insulin pump. The timing of the commercialization of this product will be based on our prioritization of resources and ongoing dialogue with the FDA.

- Mobile application - 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. We intend to launch the first generation of our mobile application in 2018, 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. We have shipped more than 60,000 insulin pumps since our initial launch in August 2012, of which nearly 56,000 pumps have been shipped within the four years ended September 30, 2017. Pump shipments are broken down by product and by fiscal quarter as follows:

| | Pump Units Shipped for Each of the Three Months Ended in Respective Years(1) (2) | | | | |
|---|---|---|---|---|---|
| | 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 | N/A | 10,111 |

| | t:slim | | | | |
|---|---|---|---|---|---|
| | March 31 | June 30 | September 30 | December 31 | Total |
| 2012 | N/A | 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 | 2,957 | 2,390 | 1,658 | 9,492 |
| 2016 | 1,255 | 1,498 | 1,965 | 76 (4) | 4,794 |

| | t:slim X2(3) | | | | |
|---|---|---|---|---|---|
| | March 31 | June 30 | September 30 | December 31 | Total |
| 2016 | N/A | N/A | N/A | 3,699 | 3,699 |
| 2017 | 2,576 | 3,209 | 3,709 | N/A | 9,494 |

| | t:flex | | | | |
|---|---|---|---|---|---|
| | March 31 | June 30 | September 30 | December 31 | Total |
| 2015 | N/A | 374 | 555 | 569 | 1,498 |
| 2016 | 371 | 493 | 389 | 354 | 1,607 |
| 2017 | 195 | 199 | 152 | N/A | 546 |

| | t:slim G4 | | | | |
|---|---|---|---|---|---|
| | March 31 | June 30 | September 30 | December 31 | Total |
| 2015 | N/A | N/A | 486 | 4,007 | 4,493 |
| 2016 | 2,416 | 2,591 | 1,542 | 289 (4) | 6,838 |
| 2017 | 45 | 19 | 7 | N/A | 71 |

(1) This table does not reflect returns or exchanges of pump products that occur in the ordinary course of business.
(2) This table does not reflect the impact of approximately 3,000 trade-ins fulfilled under the Technology Upgrade Program (discussed below) related to our commercial launch of t:slim X2.
(3) t:slim X2 includes shipments of t:slim X2 with G5, which was approved by the FDA and began shipping in August 2017.
(4) The decrease in t:slim and t:slim G4 shipments coincided with our commercial launch of t:slim X2.

***Technology Upgrade Program***

In the third quarter of 2016, we launched a Technology Upgrade Program that provided eligible t:slim and t:slim G4 customers a path towards ownership of t:slim X2 or, as of August 2017, t:slim X2 with G5, by offering customers the right to exchange their t:slim or t:slim G4 for t:slim X2 or t:slim X2 with G5, under a variable pricing structure. The Program expired on September 30, 2017.

Due to the high degree of accounting complexity, the Technology Upgrade Program created unpredictable financial results under United States generally accepted accounting principles, or GAAP, for the duration of the Program. The accounting treatment for the Program required the deferral of up to 100% of sales and cost of sales for shipments of eligible pumps beginning in the third quarter of 2016. The amount of sales and cost of sales deferred varied based on a number of factors, including the model of pump involved and the timing of the initial sales relative to the availability of certain future products. In general, the deferrals required by the Program had the effect of initially decreasing our GAAP sales, primarily in 2016, even when the number of our pump shipments increased.

We recognized the deferred amount of sales and cost of sales at the earlier of when the obligations under the Technology Upgrade 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. We recognized the majority of the remaining deferred sales and cost of sales in the quarter ended September 30, 2017, when the Program expired. At September 30, 2017, we had $0.2 million of current liabilities for deferred sales associated with the Program, as well as $0.2 million of deferred cost of sales, associated with upgrade requests received that will be fulfilled in the fourth quarter of 2017.

***Historical Financial Results***

For the nine months ended September 30, 2017 and 2016, our sales were $67.3 million and $55.3 million, respectively. For the nine months ended September 30, 2017, this included incremental net sales of $4.8 million with a corresponding increase of $3.2 million in gross profit as a result of the Technology Upgrade Program. For the nine months ended September 30, 2016, this included a deferral of sales of $8.4 million with a corresponding deferral of $1.4 million in cost of sales as a result of the Program. For the nine months ended September 30, 2017 and 2016, our net loss was $61.6 million and $68.6 million, respectively. Our accumulated deficit as of September 30, 2017 was $466.2 million.

***Trends Impacting Financial Results***

Overall, we have experienced considerable sales growth since the commercial launch of t:slim in the third quarter of 2012, while incurring operating losses since our inception. Our operating results fluctuate on a quarterly or annual basis, particularly in the periods surrounding anticipated and actual regulatory approvals, and initial stages of commercialization of our new products and those of our competitors. These fluctuations were more pronounced for the duration of the Technology Upgrade Program.

In particular, we believe that the timing of the commercial launch of t:slim X2, as well as the launch and regulatory approval of competitive products, impacted our quarterly pump shipments since the second half of 2016. In the period leading up to the commercial launch of t:slim X2 in October 2016, we believe there was an increasing number of potential customers who delayed their purchasing decision until they could include t:slim X2 and competitive products in their decision-making process. In addition, pump shipments were impacted by a decision by UnitedHealthcare that restricted a majority of their members from accessing our pumps.

In the third quarter of 2017, we believe our sales results were impacted by a number of additional factors, including:

- Hurricanes Harvey and Irma adversely impacted the normal business activities of our sales force, distributors, healthcare providers and potential customers in Texas, Florida and other impacted regions. For instance, the daily inflow to the insurance verification and approval portion of our sales pipeline decreased in early September compared to August, which coincided with the hurricanes. We also experienced a measurable decrease in our sequential monthly pump shipments for the Gulf Coast region for the month of September as compared to the month of August, whereas for all other sales regions we saw either relatively stable volumes or increases in monthly pump shipments for the same two months. In addition, we have two independent distributors located within the affected areas that experienced operational disruptions during the periods around the time of the hurricanes.

- We received FDA approval to market the t:slim X2 with G5 on August 25, 2017. Although we immediately began commercial efforts to market this product, we do not believe that third quarter pump sales benefitted significantly because of the timing of the approval within the quarter, and the number of days typically required to complete the insurance verification and approval phase of the sales process. However, we did see a meaningful increase in the daily inflow to our insurance verification and approval phase during the last two weeks of the third quarter.

- Prior to announcing our plans to launch the t:lock Connector, only a small percentage of our customers and distributors purchased infusion sets from us as compared to purchases of our cartridges. Following our announcement, we have seen, and expect to continue to see, a substantial increase in the number of infusion sets sold both in absolute terms and relative to the number of cartridges sold. In particular, the ratio of our sales volume of infusion sets relative to sales volume of cartridges during the third quarter was approximately 66%, as compared to 61% during the second quarter of 2017, 51% during the first quarter of 2017 and 31% for all of 2016.

- We continue to be subject to negative perceptions regarding our financial stability relative to that of our competitors, including concerns among healthcare providers and potential customers regarding our ability to sustain our business operations on a long-term basis. In some cases, these perceptions and concerns have caused potential customers to delay the purchase of our products or purchase competitors' products and have negatively impacted the willingness of healthcare providers to recommend our products over those of our competitors.

In addition to the factors discussed above, we expect our financial results will fluctuate in the future due to a variety of factors, including:

- market acceptance of our products and competitive products;
- the timing of the sale of our products;
- seasonality associated with summer vacations, annual deductibles and coinsurance requirements associated with most medical insurance plans utilized by our individual customers and the individual customers of our distributors;
- 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 as other companies enter or exit the diabetes medical device market;
- reimbursement decisions by third-party payors;
- the magnitude and timing of any changes to our facilities, manufacturing operations and other infrastructure; and
- anticipated and actual regulatory approvals of new products.

We expect the combined effect of the timing of our launch of t:slim X2 with G5 and our expectation that customers will largely return to their historical decision-making patterns will once again result in our sales being heavily weighted towards the second half of the year. We expect seasonality will have a similar impact on our sales in 2017 as in years prior to launch of the Technology Upgrade Program, excluding approximately $4.8 million of deferred sales and upgrade fees received associated with our Technology Upgrade Program that we recognized in the third quarter of 2017.

***Recent Developments***

*Commercial Launch of t:slim X2 with G5 Integration*

In late August 2017, the FDA approved, and we commercially launched our t:slim X2 Insulin Pump with Dexcom G5 Mobile CGM integration. The t:slim X2 with G5 is our first sensor-augmented insulin pump approved to allow users to make treatment decisions without pricking their finger. The pump conveniently displays a user's insulin delivery activity and Dexcom G5 Mobile CGM data together on one single device. The t:slim X2 with G5 has been approved for users ages six and older.

*Commercial Launch of t:lock Connector*

In September 2017, we commenced commercial sales of our insulin pump cartridges and infusion sets with our t:lock Connector. t:lock was designed to look and feel like the previous Luer-lok connector. However, t:lock incorporates a smaller inner cavity, which reduces the amount of insulin used in the process and reduces the time required to fill the infusion set tubing, improving efficiency and customer experience.

*Animas Will Discontinue the Manufacture and Sale of Insulin Pumps*

On October 5, 2017, Johnson & Johnson announced that it intends to discontinue the operations of Animas Corporation and to exit the insulin pump business entirely, and that, in connection with these activities, it designated Medtronic as a preferred partner to facilitate the transition of Animas insulin pump customers. As part of this transition, Medtronic is offering a portion of Animas customers the option of acquiring a prior-generation Medtronic insulin pump at no charge. We now offer the only alternative durable insulin pump to Medtronic in the United States. While this announcement represents a significant change within our industry, and we have experienced a recent increase in inquiries from current Animas customers following the announcement, it is too early to know how it will ultimately influence our business or the competitive landscape in which we operate, although we expect the impact may be dependent on one or more of the following factors:

- The offer to Animas customers for a free Medtronic pump is currently limited to customers with a warranty expiration date later than September 30, 2019, and the offer is not available until May 2018. It remains uncertain how many Animas customers will avail themselves of this offer.

- While Medtronic will have direct access to all Animas customers during the transition period, as those customers' pumps come up for renewal and they make new pump purchasing decisions, they may consider alternative pump options. According to recent surveys from dQ&A, when making renewal decisions, Animas customers have historically chosen their pump or a Tandem pump rather than a Medtronic offering. Recent surveys from dQ&A have also shown that only 5% of patients acquiring a Medtronic pump during the past six quarters were previous Animas customers, and 80% of new purchasers of Medtronic pumps were customers who upgraded from a current Medtronic pump rather than switching from an alternative brand. For these reasons, and based on our own customer data that shows a high number of customers switching to our products from an Animas pump, we believe our pumps are an attractive alternative to both Animas and Medtronic pumps.

- We believe one of the product features that have made Animas pumps attractive to their customers is the integration of the Animas Vibe with Dexcom's CGM technology. We now provide the only commercially available pump that is integrated with Dexcom's technology.

*Reverse Stock Split*

At a special meeting of our stockholders, held on September 7, 2017, our stockholders approved an amendment to our amended and restated certificate of incorporation to effect a reverse stock split of our issued and outstanding shares of common stock at a ratio of not less than 1-for-8 and not greater than 1-for-12, with the exact ratio to be set within that range by our board of directors, without further approval or authorization of our stockholders. On October 4, 2017, our board of directors approved the reverse stock split at a ratio of 1-for-10, and on October 9, 2017, we filed an amendment to our amended and restated certificate of incorporation with the Delaware Secretary of State to effect the reverse stock split.

Unless otherwise noted, all share and per share amounts set forth in this Quarterly Report have been adjusted to reflect the impact of the reverse stock split.

*Registered Public Offering*

On October 17, 2017, we completed a registered public offering of 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, which we refer to as the October Financing. The gross proceeds to the Company from the October Financing were approximately $16.2 million, before deducting underwriting discounts and commissions and other offering expenses payable by the Company. The Series A warrants have an exercise price of $3.50 per share, are immediately exercisable, and will expire on the 5-year anniversary of the date of issuance. The Series B warrants have an exercise price of $3.50 per share, are immediately exercisable, and will expire on the 6-month anniversary of the date of issuance. Each series of warrants, if exercised by all holders in full, may result in additional gross proceeds to us of $16.2 million.

***Additional Financing***

From inception through September 30, 2017, we have primarily financed our operations through sales of equity securities, and, to a lesser extent, debt financings. The continued growth of our business, including the expansion of our customer care infrastructure to support our growing base of customers, additional research and development activities, and the transition to our new manufacturing facility, will continue to increase our expenses and capital needs.

On the date that our financial statements in this Quarterly Report were issued, our management believed that we did not have sufficient cash to fund our operations for the next twelve months without additional financing, and therefore, we concluded there was substantial doubt about our ability to continue as a going concern within one year after the date the financial statements were issued. We expect we will be required to raise additional capital in order to continue as a going concern, meet our minimum liquidity requirements, and execute on our business strategy. We may seek additional capital from public or private offerings of our capital stock (including pursuant to our ATM offering), or we may elect to borrow additional amounts under new debt financing arrangements or from other sources. We expect 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, concerns regarding our ability to maintain the continued listing of our common stock on the NASDAQ Global Market, or NASDAQ, our current level of indebtedness and debt service costs, our conclusion that there is substantial doubt about our ability to continue as a going concern and the competitive environment in our industry.

***Term Loan Agreement***

In March 2017, we entered into Waiver and Amendment No. 4 to the Term Loan Agreement, or the Fourth Amendment. The Fourth Amendment includes a limited waiver of a potential event of default that could have resulted from the inclusion of an explanatory paragraph in the audit report of our independent registered public accounting firm included in our Annual Report on Form 10-K for the year ended December 31, 2016 ("Annual Report") that describes conditions that raise substantial doubt about our ability to continue as a going concern.

Under the Term Loan Agreement, we are required to complete one or more financings in which our aggregate gross proceeds from the sale of equity securities was at least $30.0 million, no later than January 15, 2018. As a result of the public offering of our common stock in March 2017, the sale of our common stock pursuant to our ATM offering, and the public offering of our common stock and warrants in the October Financing, we have satisfied our obligations pursuant to this equity financing covenant, although we remain subject to additional covenants.

For additional information about the Term Loan Agreement, see the section entitled "Indebtedness" below.

***Leverage from Technology Platform***

We believe we can ultimately achieve profitability because our proprietary technology platform will allow us to maximize efficiencies in the development, production, sale and marketing of multiple differentiated products. By offering products that are all based on our 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. We anticipate that the transition to our recently launched t:lock Connector will continue to increase in our sales of infusion sets. By expanding our product offerings to address people in different segments of the large and growing insulin-dependent diabetes market, we believe we can increase the productivity of our sales, clinical and marketing organization, as well as our customer support infrastructure, thereby improving our operating margin over the long term.

**Components of Results of Operations**

***Sales***

We offer products for people with insulin-dependent diabetes. We commenced commercial sales of t:slim in the United States in the third quarter of 2012. We launched our second insulin pump product, t:flex, in the second quarter of 2015, and launched our third insulin pump product, t:slim G4, in the third quarter of 2015. In October 2016, we began shipping t:slim X2, our next generation flagship product, at which time we discontinued sales of t:slim. In August 2017, we commenced commercial sales of t:slim X2 with G5 and discontinued new sales of t:slim G4. Our products currently include these insulin pumps, as well as disposable cartridges and infusion sets. We also offer accessories including protective cases, belt clips, and power adapters. Sales of accessories since commercial launch have not been significant.

We primarily sell our products through national and regional distributors on a non-exclusive basis. These distributors are generally providers of medical equipment and supplies to individuals with diabetes. Our primary end customers are people with insulin-dependent diabetes. Similar to other durable medical equipment, the primary payor is generally a third-party insurance carrier and the customer is usually responsible for any medical insurance plan copay or coinsurance requirements. We believe 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 general, we have experienced, and expect to continue to experience, 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. 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 the FDA approval or commercial launch of a new product, whether our own or 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. For example, we believe that our pump shipments were negatively impacted during the second half of 2016 and first half of 2017, as we announced the launches of t:slim X2 and the Technology Upgrade Program in the third quarter of 2016, and one of our competitors announced the future availability of two new products with financial incentives for adoption. However, we are not able to quantify the extent of the impact of these or similar events, including the launch of t:slim X2 with G5 and the transition to our t:lock Connector, on future purchasing decisions.

***Cost of Sales***

We manufacture our pumps and disposable cartridges at our manufacturing facilities 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, 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. Historically, cost of sales has also included royalty costs associated with sales of t:slim G4. In August 2017, we commenced commercial sales of t:slim X2 with G5, which has no royalty obligation, and discontinued new sales of t:slim G4. We anticipate that our cost of sales will continue to increase as our products continue to 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 that 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, we also expect our overall gross margin to fluctuate in future quarterly periods as a result of numerous factors besides those associated with production volumes. Specifically, in 2017, we are increasing our manufacturing capacity by relocating our manufacturing operations and related functions to a new facility over a period of several quarters, which may add duplicative and incremental cost in the short-term and pressure our overall gross margin for the duration of the transition. In general, we expect the gross margin on insulin pumps to be higher than the gross margin on pump-related supplies, which would be consistent with our historical experience. Other factors impacting our overall gross margin 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, 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, marketing, sales, clinical, customer care, 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, 2017. Territories are maintained by sales representatives and field clinical specialists, and supported by managed care liaisons, additional sales management and other customer support personnel. Other significant SG&A expenses 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. Although we do not contemplate an increase in the number of sales territories in the near term, we expect our SG&A expenses, including the cost of our customer care infrastructure, to increase as our customer base grows. Our SG&A expenses may also increase due to 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, including clinical trial costs, to increase as we advance our products under development and develop new products and technologies.

***Other Income and Expense***

Our other income and expense primarily consists of interest expense and amortization of debt discount and issuance costs associated with the Term Loan Agreement. At September 30, 2017, there was $82.3 million of outstanding principal under the Term Loan Agreement, which accrues interest at a rate of 11.5% per annum. We expect interest expense to increase in 2017 as a result of a higher outstanding balance under the Term Loan Agreement as compared to 2016 (see the section below entitled “Indebtedness”).

**Results of Operations**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| **(in thousands, except percentages)** | **2017** | **2016** | **2017** | **2016** |
| Sales | $ 27,003 | $ 12,293 | $ 67,306 | $ 55,336 |
| Cost of sales | 15,131 | 13,870 | 40,680 | 41,809 |
| Gross profit (loss) | 11,872 | (1,577) | 26,626 | 13,527 |
| Gross margin | 44% | (13)% | 40% | 24% |
| Operating expenses: | | | | |
| Selling, general and administrative | 20,125 | 20,683 | 65,077 | 63,768 |
| Research and development | 4,914 | 6,154 | 14,910 | 14,464 |
| Total operating expenses | 25,039 | 26,837 | 79,987 | 78,232 |
| Operating loss | (13,167) | (28,414) | (53,361) | (64,705) |
| Other income (expense), net: | | | | |
| Interest and other income | 60 | 34 | 179 | 258 |
| Interest and other expense | (2,928) | (1,434) | (8,446) | (4,177) |
| Total other expense, net | (2,868) | (1,400) | (8,267) | (3,919) |
| Net loss | $ (16,035) | $ (29,814) | $ (61,628) | $ (68,624) |

**Comparison of the Three Months Ended September 30, 2017 and 2016**

*Sales*. For the three months ended September 30, 2017, sales were $27.0 million, including the recognition of $3.3 million of pump sales originally deferred in prior periods and upgrade fees received as a result of the Technology Upgrade Program. Sales were $12.3 million for the same period in 2016, which reflect the deferral of $8.4 million of pump sales associated with the Technology Upgrade Program.

Sales of insulin pumps were $18.0 million and $6.9 million, respectively, for the three months ended September 30, 2017 and 2016. For the three months ended September 30, 2017, sales of pump-related supplies were $8.7 million, of which $3.5 million were sales of cartridges and $5.0 million were sales of infusion sets. For the three months ended September 30, 2016, sales of pump-related supplies were $5.3 million, of which $3.0 million were sales of cartridges and $2.2 million were sales of infusion sets. The ratio of the number of infusion sets shipped to the number of cartridges shipped increased to 66% in the three months ended September 30, 2017 from 27% in the comparable quarter of the prior year. Sales of accessories were not significant in either of the reported periods.

Excluding the impact of the Technology Upgrade Program, the increase in sales was primarily driven by an increase in sales of infusion sets to our distributors, as well as an increase in the sale of pump-related supplies to our growing customer base. Pump shipments were relatively flat in the three months ended September 30, 2017 at 3,868 compared to 3,896 for the same period in 2016, which we believe was the result of a number of factors including the highly competitive market, the impact of the hurricanes in the Southeast region of the United States, the timing of FDA approval of t:slim X2 with G5 within the third quarter, and negative perceptions regarding our financial stability compared to that of our competitors.

Our percentage of sales to distributors versus individual customers is principally determined by the mix of customers ordering our products within the period and whether or not we have a contractual arrangement with their underlying third-party insurance payor. Sales to distributors accounted for 74% and 67% of our total sales for the three months ended September 30, 2017 and 2016, respectively. Sales deferred under the Technology Upgrade Program decreased the percentage of sales to distributors for the three months ended September 30, 2016 by five percentage points, while there was not a significant impact to the percentage of sales to distributors in the three months ended September 30, 2017. Excluding this impact in 2016, the percentage of sales to distributors increased slightly in 2017.

*Cost of Sales and Gross Profit (Loss)*. Our cost of sales for the three months ended September 30, 2017 was $15.1 million, resulting in gross profit of $11.9 million, compared to $13.9 million cost of sales and gross loss of $1.6 million in 2016. The gross margin for the three months ended September 30, 2017 was 44% compared to negative 13% in the same period in 2016.

The increase in our gross profit (loss) for the three months ended September 30, 2017 compared to the same period in 2016 was primarily the result of the impact of the Technology Upgrade Program. During the three months ended September 30, 2017, our gross profit included a net recognition of $2.6 million of gross profit that had been deferred in prior periods, partially offset by an immaterial cost incurred for the fulfillment of upgrades. In the same period of 2016, our gross profit was reduced by a net deferral of $7.0 million of pump sales under the terms of the Program. Additionally, we recorded a $1.1 million charge in the three months ended September 30, 2016 for inventory obsolescence as a result of the commercialization of the t:slim X2 Pump, launch of the Technology Upgrade Program and associated decrease in the overall demand for our t:slim G4 Pump. This charge negatively impacted our gross margin during the three months ended September 30, 2016 by nine percentage points.

Gross profit and gross margin also increased as a result of per unit manufacturing cost improvements, including significant raw material cost reductions for our pumps and overall manufacturing efficiencies in labor and overhead for both pumps and cartridges. Other non-manufacturing costs, which primarily consist of warranty, freight and training, also reflected improvement, most notably demonstrated by a decrease in warranty expense as a result of improvements in our warranty trends and warranty replacement costs.

The gross margin was also impacted by an increase in sales of pump-related supplies, which generally have lower gross margins than our insulin pumps. However, we continue to experience a positive gross margin associated with our pump-related supplies as a whole, after first achieving a positive gross margin in the fourth quarter of 2016. We have maintained a positive quarterly gross margin since that time. 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 to distributors with the launch of our t:lock Connector.

*Selling, General and Administrative Expenses.* SG&A expenses decreased 3% to $20.1 million for the three months ended September 30, 2017 from $20.7 million for the same period in 2016.

Employee-related expenses for our SG&A functions comprise the majority of the SG&A expenses. The decrease in SG&A expenses compared to 2016 was primarily a result of a reduction in our headcount-related costs in the third quarter of 2017, compared to the same period of 2016. Our SG&A headcount declined 8% compared to 2016. Additionally, we have implemented efforts to control other spending, resulting in decreases in travel and entertainment, outside services, supplies and consulting.

*Research and Development Expenses*. R&D expenses decreased 20% to $4.9 million for the three months ended September 30, 2017 from $6.2 million for the same period in 2016. The decrease in R&D expenses was primarily the result of higher costs in 2016 associated with product pipeline development efforts, primarily related to supplies and technology license fees.

*Other Income and Expense*. Other expense for the three months ended September 30, 2017 and 2016 was $2.9 million and $1.4 million, respectively. Other expense for both periods was primarily comprised of interest expense associated with the Term Loan Agreement. The outstanding principal balances under the Term Loan Agreement were $82.3 million and $45.8 million as of September 30, 2017 and September 30, 2016, respectively. Other income for both periods presented was not significant.

**Comparison of the Nine Months Ended September 30, 2017 and 2016**

*Sales*. For the nine months ended September 30, 2017, sales were $67.3 million, including the recognition of $4.8 million pump sales originally deferred in prior periods and upgrade fees received as a result of the Technology Upgrade Program. Sales were $55.3 million for the same period in 2016, which reflect the deferral of $8.4 million pump sales associated with the Technology Upgrade Program.

Sales of insulin pumps were $43.9 million and $41.2 million, respectively, for the nine months ended September 30, 2017 and 2016. For the nine months ended September 30, 2017, sales of pump-related supplies were $23.0 million, of which $9.7 million were sales of cartridges and $13.0 million were sales of infusion sets. For the nine months ended September 30, 2016, sales of pump-related supplies were $14.2 million, of which $8.2 million were sales of cartridges and $5.8 million were sales of infusion sets. The ratio of the number of infusion sets shipped to the number of cartridges shipped increased to 60% in the nine months ended September 30, 2017 from 25% in the same period in 2016. Sales of accessories were not significant in either of the reported periods.

Excluding the impact of the Technology Upgrade Program, the decrease in pump sales was primarily driven by a 19% decrease in aggregate pump shipments from 12,520 for the nine months ended September 30, 2016 to 10,111 for the same period in 2017 for reasons similar to those described in the three month discussion above. Additionally, the period ended June 30, 2016 represented the last period in which all UnitedHealthcare members had access to our products due to their decision to designate one of our competitors as their preferred, in-network durable medical equipment provider of insulin pumps for most customers over the age of 18, which was effective July 1, 2016. The decrease in pump sales was partially offset by an increase in sales of infusion sets to our distributors, as well as overall pump-related supplies to our growing customer base.

Sales to distributors accounted for 73% and 74% of our total sales for the nine months ended September 30, 2017 and 2016, respectively.

*Cost of Sales and Gross Profit (Loss)*. Our cost of sales for the nine months ended September 30, 2017 was $40.7 million, resulting in gross profit of $26.6 million, compared to $41.8 million cost of sales and gross profit of $13.5 million in 2016. The gross margin for the nine months ended September 30, 2017 was 40% compared to 24% in the same period in 2016.

The increase in our gross profit for the nine months ended September 30, 2017 compared to the same period in 2016 was primarily the result of the Technology Upgrade Program. During the nine months ended September 30, 2017, our gross profit included $3.5 million that had been deferred in prior periods, partially offset by $0.3 million incurred for the fulfillment of upgrades. In the same period of 2016, our gross profit was reduced by a net deferral of $7.0 million of pump sales eligible under the Program. Additionally, we recorded a $1.1 million charge in the nine months ended September 30, 2016 for inventory obsolescence as described previously.

Gross profit and gross margin also increased as a result of manufacturing cost improvements, including raw material cost reductions for our pumps and increased cartridge production volumes and cartridge labor and manufacturing efficiencies, as well as a decrease in warranty expense as a result of improvements in our warranty trends and warranty replacement costs.

The gross margin was also impacted by an increase in sales of pump-related supplies, which generally have lower gross margins than our insulin pumps.

*Selling, General and Administrative Expenses.* SG&A expenses increased 2% to $65.1 million for the nine months ended September 30, 2017 from $63.8 million for the same period in 2016.

Employee-related expenses for our SG&A functions comprise the majority of the SG&A expenses. The increase in SG&A expenses was primarily the result of a $1.1 million non-cash stock-based compensation charge associated with the suspension of our ESPP in 2017, as well as other net increases in employee expenses of $0.9 million. Other SG&A expenses, including costs for outside services, marketing and promotional activities, tradeshows and travel, decreased $0.7 million between periods.

*Research and Development Expenses*. R&D expenses increased 3% to $14.9 million for the nine months ended September 30, 2017 from $14.5 million for the same period in 2016. The increase in R&D expenses was the result of an increase of $0.7 million of employee-related expenses, which includes a $0.4 million non-cash stock-based compensation charge associated with the suspension of our ESPP in 2017. This increase was offset by a reduction in non-employee-related expenses, primarily consulting and supplies, for the advancement of our product pipeline.

*Other Income and Expense*. Other expense for the nine months ended September 30, 2017 and 2016 was $8.4 million and $4.2 million, respectively. Other expense for both periods was primarily comprised of interest expense associated with the Term Loan Agreement. The outstanding principal balances under the Term Loan Agreement were $82.3 million and $45.8 million as of September 30, 2017 and September 30, 2016, respectively. Other income for both periods presented was not significant.

**Liquidity and Capital Resources**

At September 30, 2017, we had $22.5 million in cash and cash equivalents and short-term investments, which included $10.0 million of restricted cash as required by the Term Loan Agreement. At the date the financial statements in this Quarterly Report were issued, our management believed that we did not have sufficient cash to fund our operations for the next twelve months without additional financing and, therefore, we concluded there was substantial doubt about our ability to continue as a going concern within one year after the date the financial statements were issued. The financial statements included in this Quarterly Report have been prepared on a basis that assumes that we will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. This financial information and these financial statements do not include any adjustments that may result from the outcome of this uncertainty.

Historically, our principal sources of cash have included private placements and public offerings of equity securities, the Term Loan Agreement, and cash collected from product sales. Our historical cash outflows have primarily been associated with cash used for operating activities such as the expansion and support of our sales and marketing infrastructure, increase in our R&D activities, the acquisition of intellectual property, expenditures related to equipment and improvements used to increase our manufacturing capacity and improve our manufacturing efficiency, overall facility expansion, and other working capital needs.

During 2017, we have completed the following financings:

- 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.

- During the three months ended September 30, 2017, we sold 464,108 shares of common stock under our ATM offering 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.

- On October 17, 2017, we completed the October Financing, 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 the October Financing were approximately $16.2 million, before deducting underwriting discounts and commissions and other offering expenses payable by us. Each series of warrants, if exercised by all holders in full, may result in additional gross proceeds to us of $16.2 million.

Management currently believes that it will be necessary for us to raise additional funding. However, we expect 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 recent completion of a public offering of our common stock and warrants, concerns regarding our ability to maintain the continued listing of our common stock on NASDAQ, our current level of indebtedness and debt service costs, our conclusion that there is substantial doubt about our ability to continue as a going concern, the competitive environment in our industry, and accounting complexities brought about by our Technology Upgrade Program. There can be no assurance that we will be able to complete any financing on acceptable terms or at all.

We expect that, in addition to the outcome of any additional financing activities, 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 management decisions.

The following table shows a summary of our cash flows for the nine months ended September 30, 2017 and 2016:

| | Nine Months Ended September 30, | |
|---|---|---|
| **(in thousands)** | **2017** | **2016** |
| Net cash provided by (used in): | | |
| Operating activities | $ (54,495) | $ (47,591) |
| Investing activities | 4,201 | 5,873 |
| Financing activities | 17,695 | 16,586 |
| Total | $ (32,599) | $ (25,132) |

*Operating activities*. Net cash used in operating activities was $54.5 million for the nine months ended September 30, 2017, compared to $47.6 million for the same period in 2016. The increase in net cash used in operating activities was primarily associated with changes in working capital, partially offset by a decrease in net loss. The changes in working capital were primarily due to decreases in deferred revenue and guarantee liabilities associated with the Technology Upgrade Program, lower cash collections from accounts receivable and increased inventory associated with the launch of t:lock, as well as other net changes associated with the timing of payments.

*Investing activities*. 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 short-term investments of $8.5 million, partially offset by the purchase of $4.3 million of property and equipment. Net cash provided by investing activities was $5.9 million for the nine months ended September 30, 2016, which was primarily related to the purchase of $25.9 million of short-term investments and $6.2 million of property and equipment, offset by proceeds from sales and maturities of short-term investments of $38.0 million.

*Financing activities.* Net cash provided by financing activities was $17.7 million for the nine months ended September 30, 2017, which was primarily the result of net proceeds of approximately $25.7 million from the issuance of common stock, partially offset by an increase in our restricted cash balance of $8.0 million as required by the Fourth Amendment to our Term Loan Agreement. Net cash provided by financing activities was $16.6 million for the nine months ended September 30, 2016, which was primarily the result of net proceeds of $15.0 million under the Term Loan Agreement and $1.6 million in proceeds from the issuance of common stock associated with our ESPP, as well as the exercise of outstanding stock options and warrants.

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

- our ability to generate sales, the timing of those sales and the collection of receivables generated from those sales from period to period;
- the timing and amount of any additional financings, including the exercise of the warrants issued in the October Financing;
- 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;
- expansion of our manufacturing facilities and improvements in our manufacturing efficiency;
- new research and product development efforts, including clinical trial costs;
- payment of interest due under the Term Loan Agreement;
- 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 short-term cash uses or the timing or amount of cash used. We expect we will need to raise additional funding in order to continue as a going concern, meet our minimum liquidity requirements, and execute on our business strategy. We intend to seek additional capital from public or private offerings of our capital stock (including pursuant to our ATM offering) or we may elect to borrow additional amounts under new debt financing arrangements or from other sources. If we issue equity or convertible debt securities to raise additional funding, our existing stockholders may experience dilution, we may incur significant financing costs, and the new equity or convertible debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we issue debt securities to raise additional funding, we would incur additional debt service obligations, we could become subject to additional restrictions limiting our ability to operate our business, and we may be required to further encumber our assets. Our ability to continue as a going concern, meet our minimum liquidity requirements, satisfy the covenants under the Term Loan Agreement, and execute our business strategy is dependent on our ability to raise additional capital, of which there can be no assurance. If we cannot generate sufficient revenues from the sale of our products or secure additional financing on acceptable terms, we may be forced to significantly alter our business strategy, substantially curtail or modify our current operations, or cease operations altogether.

**Indebtedness**

***Term Loan Agreement***

We had $82.3 million and $81.1 million of aggregate borrowings outstanding under the Term Loan Agreement at September 30, 2017 and December 31, 2016, respectively.

Under the Term Loan Agreement, interest is payable, at our 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 to be added to the principal of the loan and subject to accruing interest. Interest-only payments are due quarterly on March 31, June 30, September 30 and December 31 of each year of the interest-only payment period, which ends on December 31, 2019. The principal balance is due in full on the maturity date of the Term Loan Agreement, which is March 31, 2020. We had elected to pay interest in cash at a rate of 11.5% per annum through September 30, 2015. Beginning October 1, 2015, we elected to pay interest in cash at a rate of 9.5% per annum and to have 2.0% per annum added to the principal of the loan. As a result, $2.3 million was added to the principal of the loan since October 1, 2015, which we refer to as PIK Loans.

The loan is collateralized by all of our assets. The principal financial covenants require that we attain minimum annual revenues of $80.0 million in 2017 and $95.0 million each year thereafter until the end of the term of the loan.

In connection with the Third Amendment, we previously agreed to pay, on the earlier of (i) the maturity date of the Term Loan Agreement, which is March 31, 2020, (ii) the date that the loan under the Term Loan Agreement becomes due, and (iii) the date on which we make a voluntary pre-payment of the loan, a financing fee equal to 3.0% of the sum of (x) the aggregate amount drawn under the Third Amendment, and (y) any PIK Loans issued in relation to the Third Amendment, which we refer to as the Back End Financing Fee.

The audit report and opinion of our independent registered public accounting firm contained in the Annual Report includes an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern. This explanatory paragraph constitutes a potential event of default under the Term Loan Agreement. On March 7, 2017, we entered into the Fourth Amendment, which included a limited waiver of the potential event of default. In consideration for the waiver, we agreed to: (i) issue the Capital Royalty Warrant, (ii) increase our restricted cash balance from $2.0 million to $10.0 million, (iii) provide Capital Royalty Partners the same information we make available to our board of directors, subject to limited exceptions, and (iv) not incur additional third party indebtedness secured solely by accounts receivable, inventory and cash. In addition, the Fourth Amendment includes a covenant requiring us to complete financings in which our gross proceeds from the sale of equity securities is at least $30.0 million, no later than January 15, 2018. As a result of the public offering of our common stock in March 2017, the sale of our common stock pursuant to our ATM offering, and the public offering of our common stock and warrants in the October Financing, we have satisfied our obligations pursuant to this equity financing covenant, although we remain subject to additional covenants.

Pursuant to the Fourth Amendment, we have agreed to increase the Back End Financing Fee to 5.0% of the entire aggregate principal amount of borrowings outstanding, including total PIK Loans issued, under the Term Loan Agreement. The Back End Financing Fee is payable at maturity of our loans and on the principal amount of any loans for which we make an optional prepayment, and may be payable in connection with asset sales not permitted under the Term Loan Agreement or in connection with a change of control. As of September 30, 2017, we had accrued $4.1 million for the Back End Financing Fee.

**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.

**Off-Balance Sheet Arrangements**

As of September 30, 2017, 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, 2017, 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 is fixed and not subject to changes in market interest rates.

Our operations are located in the United States, and nearly all of our sales since inception have been made in U.S. dollars. Accordingly, we do not currently 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 (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 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, 2017, 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, 2017.

**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, 2017 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. 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 or cash flows. However, regardless of the outcome, legal proceedings can have an adverse impact on us because of legal costs, diversion of management time and resources, and other factors.

### Item 1A. Risk Factors

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

*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.*

#### Risks Relating 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, 2017, we had an accumulated deficit of $466.2 million. To date, we have financed our operations primarily through public and private sales of our equity securities, debt financing with Capital Royalty Partners II, L.P. and its affiliated funds, or Capital Royalty Partners, and sales of our products. We have devoted substantially all of our resources to the 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, t:slim, in the third quarter of 2012. We began commercial sales of t:flex in the second quarter of 2015 and t:slim G4 in the third quarter of 2015. In October 2016, we discontinued new shipments of t:slim and launched t:slim X2, our next-generation flagship pump. In August 2017, we commenced commercial sales of t:slim X2 with G5 integration and discontinued new sales of t:slim G4. 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, 2016 and 2015, our gross profit was $23.6 million and $26.6 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 the next several years.

To implement our business strategy we need to, among other things, increase sales and gross profits of our products, maintain an appropriate customer service and support infrastructure, fund ongoing research and development activities, improve and expand our manufacturing capabilities, and obtain regulatory clearance or approval to commercialize our products currently under development. 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 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 new products. 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 pumps to generate a significant portion of our revenue, and any factors that negatively impact sales of our insulin pump products may adversely affect our business, financial condition and operating results.****

We generate a significant majority of our revenue from the sale of our insulin pump products. During 2017, our insulin pump products have included our t:slim X2, t:flex and t:slim G4 products. In August 2017, we received FDA approval for t:slim X2 with G5, and discontinued sales of t:slim G4 in connection with our launch of t:slim X2 with G5 during the three months ended September 30, 2017. Sales of our insulin pumps may be negatively impacted by many factors, including:

- the potential that other technological breakthroughs for the monitoring, treatment or prevention of diabetes may render our insulin pump products 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 facility; and
- claims that any of our insulin pump products, or any component thereof or related supplies, 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.

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, recent changes in and volatility of our stock price, concerns regarding our ability to maintain the continued listing of our common stock on the NASDAQ Global Market, or NASDAQ, perceptions about the recent completion of a public offering of our common stock and warrants, our current level of indebtedness and debt service costs, our conclusion that there is substantial doubt about our ability to continue as a going concern, the competitive environment in our industry, and accounting complexities brought about by our Technology Upgrade Program, and uncertainties regarding the regulatory environment. Any such concerns, whether actual or perceived, could cause consumers to delay the purchase of our products or to purchase competitive products.

Because we currently rely on sales of our insulin pump products to generate a significant majority of our revenue, any factors that negatively impact sales of these products, or result in sales of these products increasing at a lower rate than expected, could adversely affect our business, financial condition and operating results.

***We 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, or 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, Inc., 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 2016, Roche Diabetes Care, a division of F. Hoffman-La Roche, discontinued sales of new insulin pumps in the United States. On October 5, 2017, Johnson & Johnson announced that it is planning to discontinue the operations of Animas Corporation and to exit the insulin pump business entirely. Both Roche and Animas designated Medtronic as a preferred partner to facilitate the transition of their respective insulin pump customers. While these industry changes are significant, it is too early to know how it will influence 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 financial resources 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 diabetes industry;
- 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 that is integrated with a CGM system with a threshold suspend feature. In addition, Medtronic recently commenced the commercialization of a new insulin pump product with additional automated insulin delivery functionality and a new CGM system. Similarly, 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 may result in competitive pressures on our manufacturers, suppliers, distributors, collaboration partners and other business constituents. For example, we have entered into development agreements with Dexcom which provide us non-exclusive licenses to integrate various generations of Dexcom CGM technology with our insulin pump products. Abbott Laboratories recently announced FDA approval of a new blood glucose monitoring system, which is expected to compete with the Dexcom technology. Competitive pressures within our industry have impacted and may continue to impact our business partners, which could negatively impact our relationship with these partners, impact their ability to fulfil their 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 an adverse impact on our financial condition and operating results.

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

Our ability to achieve our strategic objectives will depend, among other things, on our ability to develop and commercialize products for the treatment of diabetes that offer distinct features and functionality, are easy-to-use, receive adequate coverage and reimbursement from third-party payors, and are more appealing than available alternatives. Our primary competitors, as well as a number of other companies, medical researchers and pharmaceutical companies are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs and other therapies for the monitoring, treatment and prevention of diabetes. Any technological 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 that companies will continue to dedicate significant resources to developing competitive products. The frequent 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 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 Technology Upgrade Program has resulted in accounting complexities that may be difficult for investors to understand and may lead to confusion when comparing our historical and future financial results.***

The Technology Upgrade Program has resulted in a number of accounting complexities that will make comparisons of our historical and future financial results more difficult. In particular, United States generally accepted accounting principles, or GAAP, prevent us from recognizing, at the time of sale, up to 100% of the sales and cost of sales associated with the sale of t:slim and t:slim G4 made to eligible customers during the term of the Technology Upgrade Program. Instead, depending on the type of pump sold, we are required to defer some or all of the sales and cost of sales until a later date, which will generally be the earlier of when our obligations under the Technology Upgrade Program are satisfied or when the program expires. The amount and timing of the deferred sales and cost of sales will depend on multiple factors that are based on future events that are difficult to estimate or predict, especially because we have not offered a similar trade-in program in the past. For example, we do not currently have sufficient history to reasonably estimate the likelihood that the trade-in rights will be exercised, or the timing of any trade-in decisions. Accordingly, it is very difficult for us to estimate the amount of the deferrals with any level of certainty, which makes it very difficult for us to predict our GAAP results, including revenues and operating margins.

Despite our efforts to explain the required accounting treatment for the Technology Upgrade Program, it is possible that investors or analysts will view the accounting treatment or the resulting impact on our GAAP financial results negatively, and there may be confusion when comparing our historical and future financial results, which may cause our stock price to decline. In addition, the complexities associated with the accounting treatment, or with the Technology Upgrade Program generally, may cause investors to avoid purchasing our common stock until the impact of the program is better understood or our financial results and trends are more predictable, which also may adversely impact our stock price.

***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 that our ability to reduce the per-unit cost of our insulin pump products and related cartridges 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 and expected warranty expenses. 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. The per unit cost of our products is significantly impacted by our overall production volumes, and any factors that cause our production volumes to decline, or to grow at a slower rate than we expect, would significantly impact our expected per unit costs. In addition, we may experience disruption in our manufacturing productivity or incur duplicative or incremental costs as we manage the planned relocation of our manufacturing facility over the next several months. Furthermore, while we currently believe our proprietary technology platform will allow us to gain efficiencies in the design and development of new products, changes in the market that require us to modify or replace our existing platform will reduce the amount of efficiency gained through our platform and increase our per unit costs. If we are unable to effectively manage our overall costs, while increasing our production volumes, we may not be able to achieve or sustain profitability, which would have an adverse impact on our business, financial condition and operating results.

***The failure of our 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 products achieving and maintaining market acceptance. Our products include t:slim X2 with G5 integration and t:flex. 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 insulin treatment 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 insulin pump products, our sales may decline or we may fail to increase our sales in line with our forecasts.

Achieving and maintaining 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 an insulin pump, 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;
- 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, especially in light of our recent and projected financial results, recent changes in and volatility of our stock price, concerns regarding our ability to maintain the continued listing of our common stock on NASDAQ, perceptions about the recent completion of a public offering of our common stock and warrants, our current level of indebtedness and debt service costs, our conclusion that there is substantial doubt about our ability to continue as a going concern, and uncertainties regarding the regulatory environment, 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 the perception that advancements could occur, in our products or the products offered by our competitors. For example, we believe that during the second half of 2016, consumers interested in purchasing our insulin pump products may have delayed or changed their purchasing decisions in anticipation of the release of a new product by one of 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 at or above our projected amounts. If our sales do not meet our sales projections, our business, financial condition and operating results could be materially and adversely affected, and we may fail to meet our strategic objectives.

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

As guidelines in setting their coverage and reimbursement policies, many third-party payors 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. More recently, 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. In addition, those 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 150 national and regional third-party payors in the United States. While we anticipate entering into additional contracts 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, any negative perceptions among third-party payors regarding our financial stability and our ability to continue to sell and service our products, may make it more difficult to enter into contracts for reimbursement with additional third-party payors. This may be especially true in light of the fact that our management believes that we do not have sufficient cash to fund our operations for the next twelve months without additional financing, and the conclusion that there is substantial doubt about our ability to continue as a going concern. 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, selling and training new customers on the use of our products, which could harm our ability to achieve our sales and service objectives.****

We have only limited experience marketing and selling our products as well as training new customers on their use. In addition, the vast majority of our existing customers are individuals with type 1 diabetes, and we have only limited experience marketing and selling our products to customers with type 2 diabetes. As a result, we may face unexpected challenges marketing and selling t:flex, which is designed to meet the needs of customers with type 2 diabetes and/or higher insulin requirements.

We expect to derive nearly all of our revenue from the sale of t:slim X2 with G5, t:flex Pumps and pump-related supplies 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 the ability of our sales and marketing organization to adequately promote, market and sell our insulin pumps 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 is the ability of our sales, clinical, marketing and customer service infrastructure to drive adoption of our products, which includes independent diabetes educators that train new customers on the use 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 light of negative perceptions regarding our financial stability, and the recent decline in our stock price, which may make it more difficult to motivate and retain key personnel. 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 that 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 could even 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, 2016, sales to approximately 40 independent distributors represented approximately 74% of our sales. While our goal is to ultimately reduce the percentage of our sales to independent distributors over time as we enter into contracts with additional third-party payors, we believe that a meaningful percentage 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. 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 is also expected to increase following our launch of the t:lock Connector for our insulin cartridge, which we expect will 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, our conclusion that, unless we successfully raise additional capital, there is substantial doubt about our ability to continue as a going concern, together with the inclusion of an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern in our independent registered public accounting firm's report contained in our financial statements for the year ended December 31, 2016, may negatively impact one or more of our distributors' interest in continuing to do business with us. None of our independent distributors has been required to sell our products exclusively and each of them may freely sell the products of our competitors. Our distributor agreements generally have one-year initial terms with automatic one-year renewal terms, and are terminable in connection with a party's material breach. 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, 2016, our two largest independent distributors collectively comprised approximately 33% 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 such a situation, 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 that 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 cause our product margins to be lower than if we directly marketed and sold our products.

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

As our clinical infrastructure expands, we expect to increasingly rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct some of our current and anticipated pre-clinical investigations and clinical trials. If we are not able to contract with or reach other mutually acceptable agreements with these third parties on a timely basis or on mutually acceptable terms, 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 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 IDCL Trial to support our development of t:slim X2 with TypeZero inControl AID algorithms. 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 TypeZero 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 TypeZero. 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.

***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 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. If demand for our products fluctuates, including as a result of the introduction of competitive products, changes in reimbursement policies, manufacturing problems, perceived safety or reliability issues with our or our competitors' products, the failure to secure regulatory clearance or approvals, or for other reasons, our ability to attract and retain customers could be harmed. In addition, the retention of current 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 would negatively impact our revenue growth and may have a material adverse effect on our business, financial condition and operating results.

***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 have a limited operating history upon which to evaluate our business and forecast our future sales and operating results and may face difficulties frequently encountered by companies early in their commercialization in competitive and rapidly-evolving markets.****

We commenced operations in 2006, and began commercial sales of t:slim in the third quarter of 2012, of t:flex in the second quarter of 2015 and of t:slim G4 in the third quarter of 2015. Accordingly, we have a limited operating history upon which to evaluate our business and forecast our future sales and operating results. More recently, our commercial launches of t:slim X2 with G5 and t:lock, the FDA approval and launch of new products by one of our competitors, and the announcement by Johnson & Johnson that it is discontinuing the operations of Animas Corporation and exiting the insulin pump business combine to make it more difficult for us to predict our future sales and operating results. In assessing our business prospects, you should consider the various risks and difficulties frequently encountered by companies early in their commercialization history 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 infrastructure to grow sales of our existing and proposed products;
- increase awareness of our brand and build loyalty among people with insulin-dependent diabetes, their caregivers and healthcare providers;
- expand our commercial operations, including complying with a broad range of legal requirements within a highly regulated industry;
- expand our manufacturing capabilities, including obtaining and maintaining regulatory approvals to operate our facilities, increasing production of products efficiently while maintaining quality standards, and adapting 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.

Due to our limited operating history, we may not have the institutional knowledge or experience to be able to effectively address these and other risks that may face our business. In addition, we may not be able to develop insights into trends that could emerge and negatively affect our business and may fail to respond effectively to those trends. 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.

***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 relating 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;
- the challenge of 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.

These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes.

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. Over the past year we have implemented several new pieces of equipment that are intended to improve our manufacturing capacity and efficiency and we expect to implement additional equipment and procedures over the next 12-18 months. However, it is possible that we may not achieve the anticipated improvements from these investments.

In addition, during 2016 we entered into a new lease agreement for an additional facility to consolidate substantially all of our manufacturing, warehousing and other operational needs, and the transition of these operations to a new facility is subject to additional risk and uncertainty, and may expose us to duplicative or incremental costs. While we have obtained the regulatory approvals necessary to commence manufacturing and shipping certain products from the new facility, we have not obtained approval to manufacture all of our products at this facility and the timing associated with obtaining the additional approvals is uncertain. Furthermore, 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 the modification of our production lines, the hiring of specialized employees, the identification of new suppliers for specific components, the implementation of additional equipment and procedures, or the development of 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 product components, and the loss of any of these suppliers, or their inability to provide us with an adequate supply of components, 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 of 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 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. Recently, we have implemented several business strategies intended to increase our future sales of infusion sets. Increases in any of our product sales, whether forecasted or unanticipated, could strain the ability of our suppliers to deliver an increasingly large supply of components in a manner that meets these 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. As a result, our ability to purchase adequate quantities of our components or products may be limited. Additionally, 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. 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. Our conclusion that, unless we successfully raise additional capital, there is substantial doubt about our ability to continue as a going concern, together with the inclusion of an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern in our independent registered public accounting firm’s report contained in our financial statements for the year ended December 31, 2016, 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 or products. Depending on a limited number of suppliers exposes us to risks, including limited control over pricing, 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 would limit our ability to meet our sales commitments, which could harm our reputation and 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 strictly-enforced 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 disruptions, 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 adversely affect our operating results.

***If we cannot manufacture and sell our new infusion set connector when anticipated, 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 our t:lock Connector, which replaces 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 anticipated 2017 sales assume that our current and future customers will begin using our new cartridges and infusion sets with t:lock in significant quantities by the end of 2017. Furthermore, our supplier of infusion sets must manufacture a variety of lengths and styles of infusion sets with t:lock that matches 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 or at all, which would negatively impact our sales and operating margins.

In addition, our independent distributors will need to agree to purchase the compatible infusion sets from us to provide to their customers. We anticipate the transition period for our direct customers and distributors to utilize their inventory on hand before transitioning to t:lock will be 90 to 120 days following its initial launch. During this period we anticipate offering both styles of cartridges and infusion sets to facilitate the transition of customer supplies. However, 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 Luer-lok style insulin cartridges that we cannot sell at standard prices or at all.

While t:lock was designed based on customer feedback, and all standard Luer-lok infusion sets that we currently offer will initially be made available with t:lock, it is possible that t:lock may not 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 may impede our ability to achieve our financial projections.

***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 either conducted, or expected to be 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, substantially all of our inventory of component supplies and finished goods are held at these locations. We take precautions to safeguard our facilities, including 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 or other disaster, such as an earthquake, fire or flood, 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 may not cover our losses in any particular case. Regardless of the level of insurance coverage, damage to our facilities may have a material adverse effect on our business, financial condition and operating results.

***The transition of our manufacturing operations to our new facility may result in further delays or expenses, which may increase our manufacturing and operating costs and require us to spend additional capital.****

We currently manufacture all of our insulin pump products and a significant portion of our cartridges at our headquarters in San Diego, California, but are in the process of transitioning all of our manufacturing operations to a nearby facility that will allow for future capacity expansion. The transition to the new manufacturing facility commenced during the second quarter of 2017 and we expect to complete the transition by the end of 2017. During the transition period we expect to experience some temporary duplication of operations to support ongoing product manufacturing, which will result in duplicative and incremental costs. In addition, while we have obtained certain governmental approvals necessary to commence manufacturing and shipping certain products from the new facility, we have not obtained approval to manufacture all of our products at this facility and the timing associated with obtaining the additional approvals is uncertain. We may continue to face significant challenges as we manage our proposed facility transition, such as additional delays or expenses, and we may be required to make additional capital expenditures relating to the new facility. We also may experience unanticipated inefficiencies as we commence manufacturing operations at the new facility, particularly during the transition period. If we fail to achieve the operating efficiencies that we anticipate from the new facility, or if we incur substantial incremental costs during the transition, our manufacturing and operating costs may be greater than we anticipate.

In September 2017, following an inspection relating to our new manufacturing 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 we intend to provide written responses to the FDA detailing these corrective and preventive actions. While we believe we will resolve this matter with the FDA without significant delay or expense, the outcome of this matter is presently uncertain. We cannot provide assurance that the FDA will conclude that our corrective and preventive actions are adequate to address the observations. 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.

We expect that the management and support of our transition to the new facility will place significant burdens on our management team, particularly in areas relating to operations, quality, regulatory, facilities and information technology. If we experience unanticipated employee turnover in any of these areas, we may not be able to effectively manage the completion of construction of the new facility or our transition and commencement of manufacturing operations when planned 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 or 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 we 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.****

t:slim X2 and t:flex 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 G4 and t:slim X2 with G5 received FDA approval under a PMA. However, there are no published studies to evaluate the safety or effectiveness of t:slim G4 or t:slim X2 with G5 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, that might have been generated in connection with other approval processes. 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 subject to mandatory product recalls, suspension or withdrawal of FDA clearance or approval, significant legal liability, and harm to our business reputation.

Any alleged illness or injury associated with any of our products or product recall may negatively impact our financial results and business prospects depending on the scope, degree of publicity, reaction of our customers, healthcare professionals, and collaborators, competitive reaction, and consumer attitudes overall. 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 or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenues 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 entered into three separate development agreements with Dexcom which provide us non-exclusive licenses to integrate various generations of Dexcom CGM technology with our insulin pump products. We currently offer t:slim G4 under an agreement that runs until January 4, 2018, with automatic one-year renewals. Our agreements with Dexcom, which provide us non-exclusive licenses to integrate Dexcom G5 and G6 technology with our insulin pump products currently run until June 2020, with automatic one-year renewals. Under certain circumstances, our agreements with Dexcom 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.

Recently, Hurricane Irma and Hurricane Harvey adversely impacted our business operations in Texas, Florida and other nearby regions. These hurricanes directly and significantly affected our sales force, healthcare providers and potential customers, as well as distribution centers operated by certain of our independent distributors. Although our business operations have generally resumed in these areas, we are currently assessing the impact these hurricanes had and will continue to have on our customers, the demand for our products in the affected areas, the effectiveness of our sales force, and the ability of our distributors to meet their obligations to us. We expect it will be several weeks before we are able to fully assess the extent of the impact and the implications to our business.

These and 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. As a result of the recent FDA clearance of our Tandem Device Updater, which enables customers to remotely update software on their insulin pumps, these risks are significantly increased.

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 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 we anticipate 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.

***If we fail to properly manage our anticipated growth, our business could suffer.***

Our rapid growth has placed, and we expect that it will continue to place, a significant strain on our management team and financial resources. For example, between December 31, 2015 and December 31, 2016 our employee base increased by approximately 23%. In addition, during 2015 and 2016 we experienced turnover among key employees in our sales, marketing, clinical, and research and development functions, including the hiring of a new Chief Commercial Officer and a new Vice President of Engineering. Our failure to manage growth effectively could cause us to misallocate management or financial resources, negatively impact our ability to attract and retain key employees, and result in losses or weaknesses in our infrastructure, which could materially adversely affect our business. Additionally, our anticipated growth and the projected evolution of our product portfolio will increase the demands placed on our suppliers, resulting in an increased need for us to manage our suppliers and monitor for quality assurance. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our business objectives.

***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, our Chief Executive Officer, as well as other key members of 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. This may be especially true during periods in which we face challenges such as financial difficulty or a reduced stock price. 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 executive 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, our outstanding equity awards, which generally are issued in the form of stock options, are significantly devalued or out of the money and less likely to be exercisable in the future. We plan 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, which may include the repricing of stock options. 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, 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 of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services, or HHS, promulgated patient privacy rules under HIPAA. These privacy rules protect 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. If we, or any of our service providers, are found to be in violation of the promulgated patient privacy rules under HIPAA, 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 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 will need to raise additional funds in the future. If these funds are not available to us, we will not have sufficient cash to fund our operations for the next twelve months.****

At September 30, 2017, we had $22.5 million in cash, cash equivalents and short-term investments, which included $10.0 million of restricted cash. At the date our financial statements in this Quarterly Report were issued, our management believed that we did not have sufficient cash to fund our operations for the next twelve months without additional financing and therefore, we concluded there was substantial doubt about our ability to continue as a going concern within one year after the date the financial statements were issued. Moreover, the continued growth of our business, including the expansion of our customer care infrastructure to support our growing base of customers, additional research and development activities, and the transition to our new manufacturing facility, will continue to increase our expenses and capital needs. In addition, the amount of our future product sales is difficult to predict and actual sales may not be in line with our forecasts. Our future capital requirements will depend on many factors, including:

- the revenue generated by sales of our insulin pump products, infusion sets and insulin cartridges, 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 in maintaining and expanding our manufacturing infrastructure, including opening our new manufacturing location and adding additional manufacturing equipment and capacity;
- the cost associated with developing and commercializing our proposed products or technologies;
- the costs associated with maintaining and expanding our customer care 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;
- expenses we incur in connection with potential litigation or governmental investigations;
- our compliance with the covenants in our Amended and Restated Term Loan Agreement with Capital Royalty Partners, which we refer to as the Term Loan Agreement;
- anticipated or unanticipated capital expenditures; and
- unanticipated general and administrative expenses.

We may in the future seek additional capital from public or private offerings of our capital stock (including our ATM offering) or we may elect to borrow additional 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 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, we may not be able to maintain our existing sales, marketing, clinical and customer care 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, or satisfy covenants in our existing indebtedness. 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 introductions. 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 of our insulin pump products and pump-related supplies, and to commercialize and sell our future products, and the number 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 financial and accounting impacts of the Technology Upgrade Program;
- 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 and reliability 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.

As a result of our recent product launches, and due to the complexities of the industry in which we operate, it will continue to be difficult for us to forecast demand for our products with any degree of certainty, which means it will be difficult for us to forecast our sales. For example, in the period leading up to the commercial launch of t:slim X2, we believe there were an increasing number of customers anticipating its availability who delayed their purchasing decisions until they could include t:slim X2 in their decision-making process.

In addition, our operating expenses will continue to increase as we expand our business. Accordingly, we may experience substantial variability in our operating results from quarter to quarter. 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 as has occurred over the past several months. Further, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

***We have concluded that we do not have sufficient cash to fund our operations for the next twelve months without additional financing and, therefore, there was substantial doubt about its ability to continue as a going concern within one year after the date the financial statements were issued, which could have a material adverse impact on our business.****

At the date the financial statements in this Quarterly Report were issued, our management believed that we did not have sufficient cash to fund our operations for the next twelve months without additional financing and, therefore, we concluded there was substantial doubt about our ability to continue as a going concern within one year after the date the financial statements were issued. The financial statements included in this Quarterly Report have been prepared on a basis that assumes that we will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

Our ability to continue as a going concern is dependent upon a number of factors, including our ability to increase our sales and gross profits, our ability to generate positive cash flow from operations, and our ability to obtain the necessary financing to meet our obligations and repay our liabilities arising from obligations that become due in the ordinary course of business. Management currently believes that it will be necessary for us to raise additional funding. However, our conclusion that there is substantial doubt about our ability to continue as a going concern may be viewed unfavorably by current and prospective investors, as well as by analysts and creditors. As a result, this conclusion may make it more difficult for us to raise the additional financing necessary to continue to operate our business. In addition, this conclusion may make it more difficult for us to sell our products and meet our sales forecasts, which may further impede our ability to raise additional financing.

If we cannot generate sufficient revenues from the sale of our products or secure additional financing on acceptable terms, we may be forced to significantly alter our business strategy, substantially curtail our current operations, or cease operations altogether.

***We may not be able to generate sufficient cash to service our indebtedness, which currently consists of our Term Loan Agreement with Capital Royalty Partners.***

At December 31, 2016, we had $81.1 million aggregate borrowings outstanding under the Term Loan Agreement with Capital Royalty Partners. Our ability to make scheduled payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves at the time a scheduled payment becomes due and our actual and projected financial and operating performance. The amount of our cash reserves and our financial and operating performance are subject to certain financial and business factors, as well as prevailing economic and competitive conditions, some of which may be beyond our control. We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, or interest on our existing or future indebtedness.

If our cash balances or cash flows from operations are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell or license our assets, sell or reduce our operations, seek additional capital on unfavorable terms, or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. Our recent and projected financial results, the explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern in the report of our independent registered public accounting firm, and general concerns among potential investors and creditors about our financial well-being may make taking such actions on commercially reasonable terms especially difficult. If we are unable to generate sufficient cash flow or are otherwise unable to obtain the funds necessary to meet required payments of principal, premium, if any, and interest on our indebtedness, we could be in default under the terms of the Term Loan Agreement.

***The Term Loan Agreement contains restrictive and financial covenants that may limit our operating flexibility, and our potential inability to comply with such covenants puts us at risk of triggering an event of default under the Term Loan Agreement.****

The Term Loan Agreement contains certain restrictive covenants that limit our ability to incur additional indebtedness and liens, merge with other companies or consummate certain changes of control, acquire other companies, engage in new lines of business, make certain investments, pay dividends, transfer or dispose of assets, amend certain material agreements or enter into various specified transactions. We may not be able to engage in any of the foregoing transactions unless we obtain the consent of Capital Royalty Partners or terminate the Term Loan Agreement.

The Term Loan Agreement also contains certain financial covenants, including minimum revenue and cash balance requirements, and financial reporting requirements. There is no guarantee that we will be able to generate sufficient cash flow or sales to meet the financial covenants or pay the principal and interest under the Term Loan Agreement. Further, there is no guarantee that future working capital, borrowings or equity financing will be available to repay or refinance the amounts outstanding under the Term Loan Agreement.

The terms of the Term Loan Agreement also require that we deliver audited financial statements that include an unqualified audit report to Capital Royalty Partners. The audit report and opinion of our independent registered public accounting firm contained in our financial statements for the year ended December 31, 2016 includes an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern. This explanatory paragraph in our auditor’s report constitutes a potential event of default under the Term Loan Agreement. As a result, in March 2017, we entered into Waiver and Amendment No. 4 to Term Loan Agreement, or the Fourth Amendment, which includes a limited waiver of a potential event of default that could have resulted from the inclusion of the explanatory paragraph in our auditor’s report. The Fourth Amendment also imposes additional restrictive and financial covenants on us, which may increase our risk of triggering defaults under the Term Loan Agreement.

In the event of a future default triggered by any violations of the covenants in the Term Loan Agreement, we will need to obtain additional waivers from Capital Royalty Partners to avoid being in default. For example, if the audit report and opinion of our independent registered public accounting firm contained in our financial statements for the year ending December 31, 2017 includes an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern, it could constitute a potential event of default under the Term Loan Agreement for which we are required to seek a waiver. If we are unable to obtain a waiver of any events of default, or an amendment to the Term Loan Agreement that would allow us to be in compliance with the terms of the agreement, an event of default would result.

In the event of our default under of the Term Loan Agreement, we may be required to repay any outstanding amounts earlier than anticipated and our capital resources may not be sufficient to meet those obligations. Further, if we are unable to repay our indebtedness and Capital Royalty Partners institutes foreclosure proceedings against our assets, we could be forced into bankruptcy or liquidation, and in such a scenario, the values that we receive for our assets could be significantly lower than the values reflected in our financial statements.

**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, 2017, our patent portfolio consisted of approximately 55 issued U.S. patents and 52 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2021 and 2035. We also have and are seeking patent protection for our proprietary technologies in other countries throughout the world. In addition, we have 10 U.S. trademark registrations and 13 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 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 be expensive and time consuming and 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. Any intellectual property dispute 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;
- 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.

Any litigation or claim against us, even those without merit, 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 and harm our reputation. Further, as the number of participants in the diabetes market increases, the possibility of intellectual property infringement claims against us 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 following our January 2014 voluntary recall of cartridges used with t:slim. 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. 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. 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 an increase 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 Premarket Approval, or 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. 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 initially received pre-market clearance for t:slim under Section 510(k) of the FDCA in November 2011. We obtained 510(k) clearances for t:connect and t:flex in February 2013 and January 2015, respectively. From time to time, we may make modifications to these products that may require a new 510(k). We have received 510(k) clearance for various modifications to t:slim and its associated cartridge. For instance, in July 2016, we received 510(k) clearance to reduce the age in our indications for use of t:slim to age six. 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 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.

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 are evaluating international expansion opportunities for a potential launch in 2018. If 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 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. 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 of 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, in which the physician has an ownership or investment interest or with which the physician has entered into a compensation arrangement;

- 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;

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

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

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 recently 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. 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, 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, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. 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.***

Beginning in 2013 through the end of 2015, the PPACA imposed, among other things, an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States. Congress suspended this tax on December 18, 2015 for two years, for sales of devices during the period January 1, 2016 through December 31, 2017. We do not believe that our products were subject to this tax (prior to its suspension) 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. The future of the medical device tax (and the PPACA generally) is uncertain. If the tax is not repealed and the two-year suspension of the tax is not extended beyond 2017, 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.

**Risks Related to our Common Stock and Warrants**

***Because of their significant stock ownership, certain of our executive officers, directors and principal stockholders will be able to exert control over our company and our significant corporate decisions.****

Based on an aggregate of 5,487,029 shares of our common stock outstanding as of September 30, 2017, our executive officers and directors, and their affiliates owned, in the aggregate, approximately 19% of the voting power of our outstanding common stock. These persons, acting together, will have the ability to significantly influence the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation, or sale of all or substantially all of our assets.

The interests of the aforementioned stockholders might not coincide with the interests of the other holders of our capital stock. This concentration of ownership may reduce the value of our common stock by, among other things:

- delaying, deferring or preventing a change of control of our company;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- causing us to enter into transactions or agreements that are not in the best interests of all stockholders.

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

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

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

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

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

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

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

As of December 31, 2016, we had federal net operating loss, or NOL, carryforwards of approximately $283.5 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, 2016, the offering that we conducted in March of 2017, either separately or together, with any future equity financing, 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.

***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. In addition, pursuant to our Term Loan Agreement with Capital Royalty Partners, we are precluded from paying any cash dividends. Accordingly, you may have to sell some or all of your shares of our common stock in order to generate cash flow from your investment. You may not receive a gain on your investment when you sell their shares of our common stock and may lose the entire amount of your 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 NASDAQ 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. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses.

In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, 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, including tantalum, tin, gold and tungsten. The number of suppliers who provide conflict-free minerals may be limited. 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. Within our supply chain, we may not be able to sufficiently verify the origins of the relevant minerals used in our products through the due diligence procedures that we implement, which may harm our reputation. We continue to investigate the use of conflict materials, if any, within our supply chain.

***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 intend 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 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 intend to take advantage of these exemptions but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. 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.

***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," 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" under the JOBS Act, 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. We could be an "emerging growth company" for up to five years from our November 2013 initial public offering. 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.

***The price of our common stock might fluctuate significantly.****

Our common stock is listed for trading on the NASDAQ Global Market under the symbol "TNDM." Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- actual or anticipated fluctuations in our quarterly financial and operating results;
- our actual or perceived need for additional capital to fund our operations and the potential associated dilution, including as a result of the issuance of warrants in the October Financing;
- perceptions about our financial stability generally, and relative to our competitors, and our ability to sustain our business operations long term;
- the reaction of investors to our conclusion that there is substantial doubt about our ability to continue as a going concern;
- overall performance of the equity markets;
- speculative trading practices of market participants;
- perceptions about the market acceptance of our products and the recognition of our brand;
- introduction of proposed products or technologies, or announcements of significant contracts, acquisitions or divestitures by us or our competitors, including the announcement that Johnson & Johnson intends to exit the insulin pump business;
- legislative, political or regulatory developments;
- issuance of securities analysts' reports or recommendations;
- additions or departures of key personnel;
- threatened or actual litigation and government investigations;
- sale of shares of our common stock by us or members of our management; and
- general economic conditions.

These and other factors might cause the market price of our common stock to fluctuate substantially, which may negatively affect the liquidity of our common stock. In addition, 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. The changes frequently appear to occur without regard to the 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 and the value of the warrants.

Securities class action litigation has often been instituted against companies following periods of volatility in the overall market and in the market price of a company's securities. This litigation, if instituted against us, could result in substantial costs, divert our management's attention and resources, and harm our business, operating results and financial condition.

***Future sales, or the perception of future sales, of shares of our common stock could materially reduce the market price of our common stock.****

Sales of our common stock, or the perception in the market that the holders of a large number of our shares intend to sell such shares, could reduce the market price of our common stock, which would impair our ability to raise future capital through the sale of additional equity securities. A substantial number of the outstanding shares of our common stock are freely tradable without restriction or further registration under the Securities Act. After taking in consideration the impact of a 1-for-10 reverse stock split that we effected on October 9, 2017, we had outstanding 10,118,659 shares of common stock as of October 23, 2017, of which approximately 1,322,789 shares are restricted securities that may be sold only in accordance with the resale restrictions under Rule 144 of the Securities Act. In addition, as of October 23, 2017, we had outstanding options to purchase 933,953 shares of common stock and warrants to purchase 9,552,753 shares of common stock that, if exercised, will result in these additional shares becoming available for sale. As of October 23, 2017, there were also 37,536 shares of our common stock reserved for future grant or issuance under our 2013 Stock Incentive Plan.

Certain holders of shares of common stock have the right, subject to various conditions and limitations, to include their shares in registration statements relating to our securities. In addition, these holders are entitled to piggyback registration rights with respect to the registration under the Securities Act of shares of our common stock. Shares of common stock registered under these registration statements can be freely sold in the public market. In the event registration rights are exercised and a large number of shares of common stock are sold in the public market, those sales could reduce the trading price of our common stock.

In the future, we may issue additional securities if we need to raise more capital. In particular, management currently believes that it will be necessary for us to raise additional funding. For example, we previously announced an up to $15 million “at-the-market” public offering of shares of our common stock. In the three months ended September 30, 2017, we had sold approximately $4.3 million of shares of common stock pursuant to our ATM offering and, accordingly, we may sell up to an additional of approximately $10.7 million shares of common stock in our ATM offering, subject to contractual limitations. The number of new shares of our common stock issued in connection with raising additional capital could constitute a material portion of the then-outstanding shares of our common stock.

***There is no public market for the warrants to purchase shares of our common stock.****

There is no established public trading market for the outstanding warrants to purchase common stock , and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the warrants on any national securities exchange or other trading market. Without an active market, we expect the liquidity of the warrants will be limited.

***Holders of our warrants will generally not have rights as a common stockholder until such holders exercise their warrants and acquire our common stock.****

Except as set forth in the warrants, holders of warrants acquire shares of our common stock upon exercise of the warrants, holders of warrants will generally not have rights with respect to the shares of our common stock underlying such warrants. Upon exercise of the warrants, the holders thereof will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

***Due to the speculative nature of warrants, there is no guarantee that it will ever be profitable for investors in the offering to exercise their warrants.****

Investors in the October Financing may exercise their right to acquire the shares of common stock underlying their Series A warrants at any time after the date of issuance by paying an exercise price of $3.50 per share, prior to their expiration on the date that is five years from the date of issuance, after which date any unexercised Series A warrants will expire and have no further value. Investors in the October Financing may exercise their right to acquire the shares of common stock underlying their Series B warrants at any time after the date of issuance by paying an exercise price of $3.50 per share, prior to their expiration on the date that is six months from the date of issuance, after which date any unexercised Series B warrants will expire and have no further value. There can be no assurance that the market price of our common stock will ever equal or exceed the exercise price of the warrants, and, consequently, whether it will ever be profitable for investors to exercise their warrants.

***Significant holders or beneficial holders of our common stock may not be permitted to exercise warrants that they hold.****

The terms of our Series A warrants and Series B warrants offered in the October Financing prohibit a holder from exercising its warrants if doing so would result in such holder (together with such holder's affiliates) beneficially owning more than 4.99% (which threshold may be decreased or increased, but not above 9.99%, at the election of the holder upon prior written notice to us) of the number of shares of common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants. As a result, a warrant holder may not be able to exercise the warrants for shares of our common stock at a time when it would be financially beneficial for a warrant holder to do so. In such circumstance, a warrant holder could seek to sell the warrants to realize value, but may be unable to do so.

***If we are unable to comply with certain continued listing requirements of NASDAQ, our common stock would be delisted from NASDAQ.****

Our common stock is currently listed on NASDAQ. In order to maintain this listing, we must satisfy minimum continued listing requirements and standards, including a minimum closing bid price requirement for our common stock. On June 14, 2017, we received notice that we had failed to meet minimum closing bid price requirement of $1.00 per share for 30 consecutive business days, which could subject our common stock to delisting. On October 24, 2017, we received notice from NASDAQ that for the 10 consecutive business days, from October 10, 2017 to October 23, 2017, our closing bid price for our common stock had been at least $1.00 per share or greater. Accordingly, we regained compliance under the NASDAQ minimum continued listing requirements. However, due to the volatility of our stock price, we cannot assure you that we will continue to satisfy the NASDAQ continued listing requirements.

***Our executive officers and directors may sell their shares of our common stock, and these sales could adversely affect our stock price.***

Sales of our common stock by our executive officers and directors, or the perception that such sales may occur, could adversely affect the market price of our common stock. Our executive officers and directors may sell our common stock in the future as part of pre-arranged trading plans or otherwise.

***Our recently implemented reverse stock split may decrease the liquidity of our common stock and result in higher transaction costs.****

The liquidity of our common stock may be negatively impacted by our implementation of a 1-for-10 reverse stock split on October 9, 2017, given the significantly reduced number of shares that are now issued and outstanding after the reverse stock split, and because our stock price did not increase commensurate with the ratio of the reverse stock split. In addition, as a result of our reverse stock split, we now have a greater number of stockholders who own “odd lots” of fewer than 100 shares of our common stock. Brokerage commission and other costs of transactions for the sale of odd lots are generally higher than the costs of transactions of more than 100 shares of common stock. Accordingly, a reverse stock split may not achieve the desired results of increasing marketability and liquidity of our common stock.

***The effective increase in the authorized number of shares of our common stock as a result of our reverse stock split could have anti-takeover implications and result in further dilution to our existing stockholders.****

In connection with the recent implementation of the reverse stock split, we maintained the total number of authorized shares of our common stock. The combination of a reverse stock split of our issued and outstanding shares, and maintaining the number of our authorized shares, has significantly increased our authorized shares relative to our issued and outstanding shares. This effective increase in the number of authorized shares will allow us to sell additional shares of our common stock (or securities convertible or exchangeable for our common stock), which would result in further dilution of our current stockholders. In addition, the effective increase in the number of authorized shares could, under certain circumstances, have anti-takeover implications. For example, the additional shares of common stock that have become available for issuance could be used by us to oppose a hostile takeover attempt or to delay or prevent changes in control or our management. Although our reverse stock split was prompted by business and financial considerations and not by the threat of any hostile takeover attempt, stockholders should be aware that our reverse stock split could facilitate future efforts by us to deter or prevent changes in control, including transactions in which our stockholders might otherwise receive a premium for their shares over then-current market prices.

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

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

| Exhibit Number | Exhibit Description | Incorporated by Reference | | | | Provided Herewith |
|---|---|---|---|---|---|---|
| | | Form | File No. | Date of First Filing | Exhibit Number | |
| 3.1 | Amended and Restated Certificate of Incorporation as currently in effect. | S-1/A | 333-191601 | 1-Nov-13 | 3.4 | |
| 3.2 | Amended and Restated Bylaws as currently in effect. | S-1/A | 333-191601 | 1-Nov-13 | 3.5 | |
| 10.1† | 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 John Cajigas, 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 John Cajigas, 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 |

† The registrant has omitted portions of the referenced exhibit pursuant to a request for confidential treatment under Rule 24b-2 promulgated under the Exchange Act.

* 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: October 26, 2017

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/ John Cajigas
John Cajigas
Executive Vice President, Chief Financial Officer and Treasurer
(on behalf of the registrant and as the registrant's Principal Financial and Accounting 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 G5 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 G5 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:

## 1. 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 G5 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 G5 System.

1.5. **DexCom CGM Smartphone App**" means the smartphone application component of the DexCom G5 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 G5 System, such as configuration settings and calibration values.

1.6. "**DexCom G5 System**" means DexCom's fifth 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 G5 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 G5 System, such as configuration settings and calibration values.

1.8. "**DexCom Sensor**" means the component of the DexCom G5 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 G5 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 G5 System or any other data generated or stored by the DexCom G5 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.

## 2. DEVELOPMENT & REGULATORY

2.1. 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.

2.2. DexCom Responsibilities. At DexCom's sole cost, DexCom intends to develop a DexCom G5 System. DexCom shall be solely responsible for all design, development, regulatory and commercialization activities associated with such DexCom G5 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 G5 System.

2.3. Costs. Each party shall bear its own costs.

## 3. OWNERSHIP & LICENSE

3.1. 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.

3.2. 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 G5 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.

3.3. 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 G5 System, or any component thereof. Tandem is not granted any right to the Raw Data received or generated by any DexCom G5 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 G5 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.

3.4. 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 G5 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.

## 4. COMMERCIALIZATION

4.1. DexCom shall have sole discretion to decide whether to complete development of and commercialize the DexCom G5 System and shall be under no obligation to complete such development or commercialization as a result of this Agreement.

4.2. 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.

4.3. If DexCom and Tandem, respectively, complete the development and commercialization of (i) the DexCom G5 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.

4.4. Tandem hereby acknowledges that DexCom may discontinue its support of the DexCom G5 System [***]. DexCom agrees to [***]. Tandem further acknowledges that DexCom has no obligation to [***].

## 5. Representations and Warranties

5.1. 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.

5.2. 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.

5.3. 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.

## 6. Confidentiality

6.1. 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:

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

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

6.1.3. 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

6.1.4. 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.

6.2. 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).

6.3. 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.

6.4. 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.

## 7. Indemnification and Defense of Infringement

7.1. 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 [***].

7.2. 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 [***].

7.3. 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.

7.4. 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 [***].

7.5. 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 [***].

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

## 8. TERM AND TERMINATION

8.1. 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**").

8.2. 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 [***].

8.3. Effect of Termination.

8.3.1. 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.

8.3.2. 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.

## 9. 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.

## 10. MISCELLANEOUS

10.1. 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).

10.2. 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.

10.3. 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.

10.4. 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.

10.5. 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<br>11045 Roselle St.<br>San Diego, CA 92121<br>Attn: Chief Executive Officer<br>with copy to: General Counsel |
| DexCom: | DexCom, Inc. |

6340 Sequence Drive
San Diego, CA 92121
Attn: Legal Department

10.6. 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.

10.7. 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.

10.8. 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.

10.9. 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.

10.10. 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.

10.11. 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.

10.12. 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.

10.13. 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 G6 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

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 and CEO

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: October 26, 2017

**Exhibit 31.2**

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

I, John Cajigas, certify that:

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

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

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

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

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

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

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

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

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

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

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

Tandem Diabetes Care, Inc.

By: /s/ John Cajigas
John Cajigas
Executive Vice President, Chief Financial Officer and Treasurer

Dated: October 26, 2017

**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, 2017, 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: October 26, 2017

/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, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John Cajigas, 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: October 26, 2017

/s/ John Cajigas
John Cajigas
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.*