TANDEM DIABETES CARE INC
Form 10-Q
July 28, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Quarterly Period Ended June 30, 2016

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 x 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 x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

As of July 25, 2016, there were 30,613,826 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)

	June 30, 2016 (Unaudited)	December 31, 2015 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 30,250	$43,088
Restricted cash	2,000	2,000
Short-term investments	24,068	28,018
Accounts receivable, net	9,426	14,055
Inventory	21,692	17,543
Prepaid and other current assets	3,445	2,280
Total current assets	90,881	106,984
Property and equipment, net	16,242	15,526
Patents, net	1,947	2,110
Other long-term assets	120	105
Total assets	$ 109,190	$124,725
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,841	$5,234
Accrued expense	2,177	2,121
Employee-related liabilities	10,952	11,761
Deferred revenue	1,763	1,822
Other current liabilities	5,332	5,582
Total current liabilities	27,065	26,520
Notes payable—long-term	44,398	29,275
Deferred rent—long-term	2,207	2,743
Other long-term liabilities	3,447	2,719
Total liabilities	77,117	61,257
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.001 par value; 100,000 shares authorized as of June 30, 2016 and December 31, 2015, 30,613 and 30,255 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively.	31	30
Additional paid-in capital	391,981	384,551
Accumulated other comprehensive income	3	20

Accumulated deficit	(359,942)	(321,133)
Total stockholders' equity	32,073	63,468
Total liabilities and stockholders' equity	$109,190	$124,725

See accompanying notes to unaudited condensed financial statements.

TANDEM DIABETES CARE, INC.

CONDENSED STATEMENTS OF OPERATIONS and comprehensive loss

(Unaudited)

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Sales	$22,985	$15,706	$43,043	$28,014
Cost of sales	14,809	10,905	27,939	20,406
Gross profit	8,176	4,801	15,104	7,608
Operating expenses:				
Selling, general and administrative	21,087	19,599	43,084	38,954
Research and development	4,142	3,873	8,310	7,735
Total operating expenses	25,229	23,472	51,394	46,689
Operating loss	(17,053)	(18,671)	(36,290)	(39,081)
Other income (expense), net:				
Interest and other income	107	61	225	160
Interest and other expense	(1,379)	(923)	(2,744)	(1,821)
Total other expense, net	(1,272)	(862)	(2,519)	(1,661)
Net loss	$(18,325)	$(19,533)	$(38,809)	$(40,742)
Other comprehensive loss:				
Unrealized gain (loss) on short-term investments	$(37)	$(39)	$(17)	$29
Comprehensive loss	$(18,362)	$(19,572)	$(38,826)	$(40,713)
Net loss per share, basic and diluted	$(0.60)	$(0.65)	$(1.28)	$(1.47)
Weighted average shares used to compute basic and diluted net loss per share	30,489	29,902	30,392	27,723

See accompanying notes to unaudited condensed financial statements.

TANDEM DIABETES CARE, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Six Months Ended June 30,	
	2016	2015
Operating activities		
Net loss	$(38,809)	$(40,742)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	2,718	2,414
Interest expense related to amortization of debt discount and debt issuance costs	142	71
Provision for allowance for doubtful accounts	601	(100)
Provision for inventory reserve	—	101
Payment in kind interest accrual of notes payable	440	—
Amortization of discount on short-term investments	(19)	(37)
Stock-based compensation expense	5,828	7,033
Gain (loss) on disposal of property and equipment	(84)	14
Other	(21)	(77)
Changes in operating assets and liabilities:		
Accounts receivable, net	4,028	279
Inventory	(4,108)	(2,892)
Prepaid and other current assets	(1,165)	(249)
Other long-term assets	(15)	(17)
Accounts payable	1,731	1,388
Accrued expense	78	(933)
Employee-related liabilities	(809)	(1,045)
Deferred revenue	(58)	198
Other current liabilities	403	(47)
Deferred rent	(453)	(308)
Other long-term liabilities	135	769
Net cash used in operating activities	(29,437)	(34,180)
Investing activities		
Purchase of short-term investments	(22,657)	(58,993)
Proceeds from sales and maturities of short-term investments	26,750	43,450
Purchase of property and equipment	(4,048)	(2,351)
Purchase of patents	—	(74)
Net cash provided by (used in) investing activities	45	(17,968)
Financing activities		
Issuance of notes payable, net of issuance costs	14,994	—
Proceeds from public offering, net of offering costs	—	64,862
Proceeds from issuance of common stock	1,560	2,031
Net cash provided by financing activities	16,554	66,893
Net (decrease) increase in cash and cash equivalents	(12,838)	14,745
Cash and cash equivalents at beginning of period	43,088	31,176
Cash and cash equivalents at end of period	$30,250	$45,921
Supplemental disclosures of cash flow information		

Interest paid	$2,099	$1,735
Supplemental schedule of noncash investing and financing activities		
Lease incentive - lessor-paid tenant improvements	$—	$933
Debt issuance cost included in other long-term liabilities	$454	$—
Property and equipment included in accounts payable	$595	$1,510

See accompanying notes to unaudited condensed financial statements.

TANDEM DIABETES CARE, INC.

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 a family 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 currently manufactures and sells three insulin pump products in the United States that are designed to address large and differentiated needs of the insulin-dependent diabetes market:

- the t:slim® Insulin Delivery System, or t:slim, the Company's flagship product that can easily and discreetly fit into a pocket,
- the t:flex® Insulin Delivery System, or t:flex, for people with greater insulin needs, and
- the t:slim G4™ Insulin Delivery System, or t:slim G4, a Continuous Glucose Monitoring ("CGM") enabled pump with touch-screen simplicity.

The Company designed and commercialized its products based on its proprietary technology platform and consumer-focused approach. 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.

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 footnotes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, from which the balance sheet information herein was derived but excludes disclosures required by GAAP for complete financial statements.

2. Summary of Significant Accounting Policies

There have been no significant changes in our significant accounting policies during the six months ended June 30, 2016, as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015.

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 notes as of the date of the financial statements. Actual results could materially differ from those estimates and assumptions.

Restricted Cash

Restricted cash as of June 30, 2016 and December 31, 2015 was comprised of a $2.0 million minimum cash balance requirement in connection with the Company's Term Loan Agreement, as amended by Consent and Amendment Agreement, dated June 20, 2014, Omnibus Amendment Agreement No. 2, dated February 23, 2015 and Amendment No. 3 to Term Loan Agreement, dated January 8, 2016 with Capital Royalty Partners II, L.P. and its affiliate funds ("Capital Royalty Partners") (as amended, 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, generally, for receivables greater than 120 days past due and based upon a specific review of other outstanding invoices. Uncollectible accounts are written off against the allowance after appropriate collection efforts have been exhausted and when it is deemed that a balance is uncollectible.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, accrued expense, and employee-related liabilities are reasonable estimates of their fair values because of the short-term nature of these assets and liabilities. Short-term investments and foreign exchange forward contracts that are not designated as hedges 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.

Revenue Recognition

Revenue is generated 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. These criteria are applied as follows:

The evidence of an arrangement generally consists of contractual arrangements with distributors, third-party insurance payors or direct customers.

Transfer of title and risk and rewards of ownership are passed upon shipment of the pump to distributors or upon delivery to the customer.

The selling prices are fixed and agreed upon based on the contracts with distributors, the customer and contracted insurance payors, if applicable. For sales to customers associated with insurance providers with whom there is no contract, revenue is recognized upon collection of cash, at which time the price is determinable. The Company generally does not offer rebates to its distributors and customers.

The Company considers the overall creditworthiness and payment history of the distributor, customer and the contracted insurance payor in determining whether collectability is reasonably assured.

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) if the arrangement includes a general right of return relative to the delivered item(s), 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 Company uses 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. This service is deemed an undelivered element at the time of the insulin pump sale. Because the Company has neither VSOE nor TPE for this deliverable, 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 this element at the time of sale and is recognizing the revenue over the four-year hosting period. At June 30, 2016 and December 31, 2015, $1.3 million and $1.1 million, respectively, were recorded as deferred revenue for the t:connect hosting service. 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 amounts recorded on the Company's balance sheet for product return allowance were $0.2 million and $0.3 million at June 30, 2016 and December 31, 2015, 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 replacement product 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 could have a material impact on the Company's estimated liability.

At June 30, 2016 and December 31, 2015, the warranty reserve was $4.6 million and $3.5 million, respectively. The following table provides a reconciliation of the change in product warranty liabilities through June 30, 2016 (in thousands):

Balance at December 31, 2015	$3,547
Provision for warranties issued during the period	3,863
Settlements made during the period	(4,003)
Increases in warranty estimates	1,242
Balance at June 30, 2016	$4,649
Current portion	$2,018
Non-current portion	2,631
Total	$4,649

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 2013 Stock Incentive Plan ("2013 Plan") and shares issued under the 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 including volatility, expected term, and risk-free rate. For awards that vest based on 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 dilutive common share equivalents outstanding for the period determined using the treasury stock method. Dilutive common share equivalents are comprised of warrants, potential awards granted pursuant to the ESPP, and options outstanding under the Company's other equity incentive plans. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

Potentially dilutive securities not included in the calculation of diluted net loss per share (because inclusion would be anti-dilutive) are as follows (in thousands, in common stock equivalent shares):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Warrants for common stock	990	990	990	990
Common stock options	2,932	2,042	2,623	2,042
ESPP	17	17	9	9
	3,939	3,049	3,622	3,041

Reclassifications

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

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board (“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 an Accounting Standards Update on changing certain aspects of accounting for share-based payments to employees. The new guidance will require all income tax effects of awards to be recognized in the income statement when the awards vest or are settled. It also will allow an employer to repurchase more of an employee’s shares than it can today for tax withholding purposes without triggering liability accounting, and to make a policy election to account for forfeitures as they occur. The guidance is effective for public business entities for fiscal years beginning after December 15, 2016, and interim periods within those years. Early adoption is permitted, but all of the guidance must be adopted in the same period. The Company is in the process of assessing the impact of the adoption of the standard on its financial statements.

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 today's accounting. The new guidance also eliminates today's real estate-specific provisions for all entities. The standard is effective for public business entities 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 April 2015, the FASB issued ASU No. 2015-03 amended requirements that require debt issuance costs, related to a recognized debt liability, to be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, effective for the Company beginning January 1, 2016 and applied retroactively for all consolidated balance sheets presented. The Company applied the amended presentation requirements in the first quarter 2016, which resulted in the reclassification of $0.4 million of debt issuance costs in the Company's balance sheet from other long-term assets to long-term notes payable at December 31, 2015.

In May 2014, FASB and the International Accounting Standards Board issued a comprehensive new revenue recognition standard that will supersede existing revenue guidance under U.S. GAAP and International Financial Reporting Standards. The 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. This may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. On July 9, 2015, the FASB approved a one-year deferral of the effective date of the standard to December 15, 2017 and early application is permitted, but not before the original effective date of December 15, 2016. The Company is in the process of assessing the impact of the adoption of the standard on its financial statements.

3. Short-Term Investments

The Company invests in various securities, principally in debt instruments of financial institutions and corporations. The following represents a summary of the estimated fair value of short-term investments at June 30, 2016 and December 31, 2015 (in thousands):

At June 30, 2016	Maturity (in years)	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Available-for-sale investment securities:					
Commercial paper	Less than 1	$ 23,703	$ 4	$ (1)	$ 23,706
Trading securities:					
Mutual funds held for nonqualified deferred compensation plan participants		$ 346	$ 18	$ (2)	$ 362
Total		$ 24,049	$ 22	$ (3)	$ 24,068

At December 31, 2015	Maturity (in years)	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Available-for-sale investment securities:					
Commercial paper	Less than 1	$ 21,712	$ 23	$ —	$ 21,735
US Treasuries	Less than 1	2,035	—	(1)	$ 2,034
Government-sponsored enterprise securities	Less than 1	4,029	—	(2)	4,027
		$ 27,776	$ 23	$ (3)	$ 27,796
Trading securities:					
Mutual funds held for nonqualified deferred compensation plan participants		$ 224	$ 1	$ (3)	$ 222
Total		$ 28,000	$ 24	$ (6)	$ 28,018

4. Inventory

Inventory consisted of the following (in thousands):

	June 30, 2016	December 31, 2015
Raw materials	$12,071	$ 10,606
Work in process	4,595	3,394
Finished goods	5,026	3,543
Total	$21,692	$ 17,543

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 an 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 June 30, 2016 and December 31, 2015, and indicates the fair value hierarchy of the valuation techniques utilized by the Company to determine such fair value (in thousands):

		Fair Value Measurements at June 30, 2016		
		(Level 1)	(Level 2)	(Level 3)
Assets				
Cash equivalents (1)	$13,639	$13,639	$—	$ —
Commercial paper	23,706	—	23,706	—
Mutual funds held for nonqualified deferred compensation plan participants (2)	362	362	—	—
Total assets	$37,707	$14,001	$23,706	$ —
Liabilities				
Deferred compensation (2)	$362	$362	$—	$ —
Total liabilities	$362	$362	$—	$ —

		Fair Value Measurements at December 31, 2015		
		(Level 1)	(Level 2)	(Level 3)
Assets				
Cash equivalents (1)	$23,402	$23,402	$—	$ —
Commercial paper	21,735	—	21,735	—
Mutual funds held for nonqualified deferred compensation plan participants (2)	222	222	—	—
US Treasuries	2,034	2,034	—	—
Government-sponsored enterprise securities	4,027	—	4,027	—
Total assets	$51,420	$25,658	$25,762	$ —
Liabilities				
Deferred compensation (2)	$222	$222	$—	$ —

Total liabilities	$222	$222	$—	$ —

(1) Cash equivalents included money market funds and commercial paper with a maturity of three months or less from the date of purchase.

(2) Deferred compensation plans are compensation plans directed by the Company and structured as a Rabbi Trust for 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 securities during the six months ended June 30, 2016.

6. Term Loan Agreement

In January 2016, the Company entered into Amendment No. 3 to Term Loan Agreement with Capital Royalty Partners ("Third Amendment"), which was previously amended by Consent and Amendment Agreement, dated June 20, 2014, and Omnibus Amendment Agreement No. 2, dated February 23, 2015.

Under the Term Loan Agreement, the Company had aggregate borrowings outstanding of $30.2 million (such amount, the "First Tranche") as of December 31, 2015. Under the Third Amendment, the Company borrowed $15.0 million (such amount, the "Second Tranche") in January 2016, and the Third Amendment provides the Company with a one-time option to draw up to an additional $35.0 million in increments of $5.0 million on or before December 31, 2016 (such amount, to the extent drawn, the "Third Tranche").

The other principal terms of the Term Loan Agreement were not amended by the Third Amendment. Accordingly, interest continues to be 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 continue to be 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 continues to be due in full at the end of the term of the loan, which is March 31, 2020 (the "Maturity Date"). The Term Loan Agreement provides for prepayment fees in an amount equal to one percent (1.0%) of the outstanding balance of the loan if the loan is repaid prior to March 31, 2017, after which there is no prepayment fee. The term loan is collateralized by all assets of the Company. The principal financial covenants continue to require that the Company attain minimum annual revenues of $65.0 million in 2016, $80.0 million in 2017 and $95.0 million each year thereafter until the Maturity Date. At June 30, 2016, the Company was in compliance with all of the covenants in the Term Loan Agreement.

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 to have 2.0% per annum added to the principal of the loan. As a result, $440,000 and $153,000 was added to the principal of the loan for the six months ended June 30, 2016 and the three months ended December 31, 2015, respectively. The Company had $45.6 million of aggregate borrowings outstanding under the Term Loan Agreement as of June 30, 2016.

Pursuant to the Third Amendment, the Company has 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 three percent (3.0%) of the sum of (x) the aggregate amount of the Second Tranche and Third Tranche drawn, and (y) any PIK Loans issued in relation to the Second Tranche and Third Tranche (collectively, the "Back End Financing Fee"). As of June 30, 2016 the Company had accrued $0.5 million for the Back End Financing Fee in other long-term liabilities and as contra-debt in notes payable--long-term on the accompanying balance sheet.

The Company treated this amendment as a modification. The present value of the future cash flows under the Third 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 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 Third Amendment using the effective interest method.

7. Stockholders' Equity

Public Offering

In the first quarter of 2015, the Company completed a public offering of 6,037,500 shares of its common stock at a public offering price of $11.50 per share. Net cash proceeds from the public offering were approximately $64.9 million, after deducting underwriting discounts, commissions and offering expenses paid by the Company.

Shares Reserved for Future Issuance

The following shares of the Company's common stock were reserved for future issuance at June 30, 2016:

Shares underlying outstanding warrants	990,031
Shares underlying outstanding stock options	6,774,815
Shares authorized for future equity award grants	2,058,291
Shares authorized for issuance as ESPP awards	520,420
	10,343,557

The Company issued 108,299 shares of its common stock upon the exercise of stock options and warrants during the six months ended June 30, 2016, and issued 260,091 shares of its common stock upon the exercise of stock options and warrants during the year ended December 31, 2015.

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 250,367 shares of the Company's common stock purchased under the ESPP during the six months ended June 30, 2016, and 302,171 shares of the Company's common stock purchased under the ESPP during the year ended December 31, 2015.

Stock-Based Compensation

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

	Stock Option			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Weighted average grant date fair value (per share)	$4.36	$7.24	$3.79	$7.67
Risk-free interest rate	1.4 %	1.7 %	1.4 %	1.7 %
Expected dividend yield	0.0 %	0.0 %	0.0 %	0.0 %
Expected volatility	56.0%	66.1%	55.5%	67.4%
Expected term (in years)	6.1	6.1	6.1	6.1

	ESPP			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Weighted average grant date fair value (per share)	$2.69	$4.98	$2.69	$4.98
Risk-free interest rate	0.6 %	0.3 %	0.6 %	0.3 %
Expected dividend yield	0.0 %	0.0 %	0.0 %	0.0 %
Expected volatility	56.9%	62.1%	56.9%	62.1%
Expected term (in years)	1.3	1.3	1.3	1.3

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Cost of sales	$269	$307	$509	$631
Selling, general & administrative	2,422	2,602	4,672	5,580
Research and development	338	351	648	822
Total	$3,029	$3,260	$5,829	$7,033

The total stock-based compensation capitalized as part of the cost of inventory was $0.2 million and $0.1 million at June 30, 2016 and December 31, 2015, respectively.

8. Collaborations

DexCom Development and Commercialization Agreement

In February 2012, the Company entered into a Development and Commercialization Agreement (the “DexCom Agreement”) with DexCom, Inc. (“DexCom”) for the purpose of collaborating on the development and commercialization of an integrated system which incorporates t:slim Insulin Delivery System with DexCom’s proprietary continuous glucose monitoring system.

Under the DexCom Agreement, the Company paid DexCom $1.0 million at the commencement of the collaboration in 2012, $1.0 million in 2014 upon the achievement of t:slim G4 pre-market approval ("PMA") submission to the U.S. Food and Drug Administration ("FDA") and an additional $1.0 million in September 2015 upon obtaining approval of the PMA submission from the FDA. All payments were recorded as research and development costs in their respective years.

Additionally, upon commercialization and as compensation for the non-exclusive license rights, under the original DexCom Agreement the Company agreed to pay DexCom a royalty calculated at $100 per integrated system sold.

In September 2015, the Company entered into an amendment to the DexCom Agreement (the "Amendment"). Pursuant to the Amendment, in lieu of the $100 royalty payment for each integrated system sold, the Company will commit $100 of each t:slim G4 integrated system sold to incremental marketing activities associated with t:slim G4 integrated systems that are in addition to a level of ordinary course marketing activities or marketing activities to support other Company and DexCom jointly funded development projects. The committed marketing fund is recorded as an increase to cost of sales and current liability in the period that the related t:slim G4 sale is recorded. The Company has recorded such marketing fund activities of $0.3M and $0.5M for the three and six months ended June 30, 2016, respectively. As of June 30, 2016 and December 31, 2015, the Company has recorded a marketing fund liability of $0.8 million and $0.4 million, respectively, in other current liabilities on the accompanying balance sheet.

JDRF Collaboration

In January 2013, the Company entered into a Research, Development and Commercialization Agreement ("JDRF Agreement") with JDRF to develop the t:dual Infusion System, a first-of-its-kind, dual-chamber infusion pump for the management of diabetes. According to the terms of the JDRF Agreement, JDRF would provide research funding of up to $3.0 million based on the achievement of research and development milestones, not to exceed research costs incurred by the Company. Any intellectual property developed by either party in the performance of the agreement would be owned or exclusively licensed by the Company.

Payments that the Company received to fund the collaboration efforts under the terms of the JDRF Agreement were recorded as restricted cash and current and long-term liabilities. The liabilities were recognized as an offset of research and development expenses straight-line over the remaining months until anticipated completion of the final milestone, only to the extent that the restricted cash was utilized to fund such development activities.

In February 2016, the Company and JDRF entered into a termination agreement ("JDRF Termination Agreement"), where both parties mutually terminated the JDRF Agreement. As of December 31, 2015, milestone payment achievements totaled $0.7 million, and research and development costs were offset cumulatively by $0.5 million. Under the terms of the JDRF Termination Agreement, the Company agreed to repay JDRF $0.7 million, which is equal to the amount of milestone payments received by the Company to date. The Company accrued for the repayment in other current liabilities on the accompanying balance sheet as of December 31, 2015 and repaid such

amount during the first quarter of 2016.

9. Commitments and Contingencies

From time to time, the Company may be subject to legal proceedings or 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 believed to be probable that a loss has been incurred and the amount 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 each of June 30, 2016 and December 31, 2015, there were no material matters for which the negative outcome was considered probable or estimable.

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, 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 ne such terms, or other comparable terminology. Forward-looking statements also include the assumptions underlying or relating to such statements.

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 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 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 Stock 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 a family of products for people with insulin-dependent diabetes. Our 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 currently manufacture and sell three insulin pump products in the United States that are designed to address large and differentiated segments of the insulin-dependent diabetes market:

- the t:slim Insulin Delivery System, or t:slim, our flagship product that can easily and discreetly fit into a pocket,
- the t:flex Insulin Delivery System, or t:flex, for people with greater insulin needs, and
- the t:slim G4 Insulin Delivery System, or t:slim G4, the first Continuous Glucose Monitoring, CGM, enabled pump with touch-screen simplicity.

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. This 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 technology platform features our patented Micro-Delivery technology, a miniaturized pumping mechanism which 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 touch screen and a micro-USB connection that supports both a rechargeable battery and t:connect, our custom cloud-based data management application that provides a fast, easy and visual way to display therapy management data from the pump and supported blood glucose meters.

In July 2016, we received clearance from the FDA to begin offering the Tandem Device Updater, which is a Mac® and PC-compatible tool for the remote update of Tandem insulin pump software. This tool allows us to provide our customers access to new and enhanced features faster than the industry has been able to in the past, and separate from the typical multi-year warranty hardware replacement cycle. The first use of the Tandem Device Updater will be for deployment of the latest t:slim Insulin Pump software to in-warranty t:slim Pumps purchased before April 2015. Future software improvements and enhancements will be implemented through the Tandem Device Updater as they are cleared for commercial distribution.

We have a number of products and product enhancements that we plan to launch in the next 12 months, pending appropriate regulatory clearance. In the fourth quarter of 2016, we plan to begin shipping the t:slim X2™ Insulin Pump, a next generation t:slim Pump that is intended to be updatable with PMA classified software, such as CGM integration, using the Tandem Device Updater. Also, during 2017 we plan to launch G5 sensor integration for the t:slim X2 Pump.

We began commercial sales of our first product, t:slim, in August 2012. During 2015, we commenced commercial sales of two additional insulin pumps: t:flex in May 2015 and t:slim G4 in September 2015. Since inception, we have derived nearly all of our revenue from the sale 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 42,000 insulin pumps since the initiation of our commercial efforts in 2012. Pump shipments are broken down by product and by quarter as follows:

	Pump Units Shipped for Each of the Three Months Ended in Respective Years[1]				
	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	N/A	N/A	2,753
	t:flex				
	March 31	June 30	September 30	December 31	Total
2015	N/A	374	555	569	1,498
2016	371	493	N/A	N/A	864
	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	N/A	N/A	5,007
	Total				

	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)]	2,487	3,331	3,431	6,234	15,483
2016	4,042	4,582	N/A	N/A	8,624

(1) This table does not reflect returns or exchanges of pump products that occurred in the ordinary course of business.
(2) During the fourth quarter of 2015, 148 t:slim pumps and two t:flex pumps originally shipped in the third quarter of 2015 were exchanged for t:slim G4 pumps under a limited product exchange program. Amounts for the fourth quarter of 2015 in the table above are adjusted to reflect the impact of the exchange program.

For the three months ended June 30, 2016 and 2015, our sales were $23.0 million and $15.7 million, respectively. For the three months ended June 30, 2016 and 2015, our net loss was $18.3 million and $19.5 million, respectively. For the six months ended June 30, 2016 and 2015, our sales were $43.0 million and $28.0 million, respectively. For the six months ended June 30, 2016 and 2015, our net loss was $38.8 million and $40.7 million, respectively.

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. 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. 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. For example, 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. However, in most circumstances in which we do not have contracts established with third-party payors, we utilize our network of national and regional distributors to service our customers.

We believe we can ultimately achieve profitability because our proprietary technology platform will allow us to maximize efficiencies in the development, production and sale of our products. By offering a family of products, all of which are based on our proprietary technology platform, we believe we can develop and bring to market products more rapidly, while significantly reducing our 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 reduce our product costs and drive operational efficiencies. Further, we expect to continue to increase production volume and to reduce the per-unit production overhead cost for our pump products and their associated disposable cartridges over time. By expanding our product offerings to address 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, and utilize the expertise of our customer, technical and support services, thereby improving our operating margin.

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 may fluctuate on a quarterly or annual basis in the future, in particular in the periods surrounding anticipated and actual regulatory approvals and initial stages of commercialization of new products, and our growth or operating results may not be consistent with predictions made by securities analysts.

In anticipation of our future product launches over the next 12 months, we are offering a Technology Upgrade Program that provides eligible t:slim and t:slim G4 customers a path forward to the t:slim X2 platform under a variable pricing structure. The accounting treatment for this program will include the deferral of some portion, up to 100%, of revenues and cost of goods sold for shipments of eligible pumps beginning in the third quarter of 2016. The opportunity for a customer to receive future upgrades and services represents a right of return or guarantee at the time of the initial product purchase. We have not offered an upgrade program in the past and do not have sufficient history with similar upgrade programs to estimate the number of customers that will participate. As a result, we anticipate that sales and cost of goods sold for all eligible t:slim and t:slim G4 shipments will be subject to deferral. The amount of revenue and cost of goods sold deferred will vary based on type of the original pump and timing of the initial sales relative to the availability of future products. We expect to recognize the deferred amount of sales and costs of goods sold at the earlier of when the Company’s obligations under the Upgrade Program are satisfied or when the Upgrade Program expires on September 30, 2017. If a customer elects to participate in the Upgrade Program, the Company will recognize upgrade fees that it receives and the associated costs at the time of fulfilling the given obligation.

We believe that the timing of the commercial launch of the t:slim X2 pump may negatively impact our aggregate pump shipments during the three months ended September 30, 2016 and may cause further fluctuations throughout the duration of the Technology Upgrade Program. In particular, in the period leading up to the commercial launch of the t:slim X2 pump, there will be an increasing number of customers anticipating its availability and may delay their purchasing decisions until they could include the t:slim X2 in their decision-making process.

On June 30, 2016, we entered into a Lease Agreement for additional facilities to consolidate substantially all of our manufacturing, warehousing and other operational needs during 2017. The initial lease term is expected to commence on or about December 1, 2016 for an 84-month period. The initial monthly base rent for the premises is approximately $45,000 per month and will increase annually by 3.0%. No base rent will be due under the lease for a seven-month period, commencing on the later of February 1, 2017 or the actual lease commencement date. We are also required to pay certain ongoing expenses associated with the facility throughout the duration of the Lease Agreement, as well as a fee associated with access to an affiliated amenities center. The Lease Agreement allows for a tenant improvement allowance, the TI Allowance, of up to approximately $3.4 million to be applied to non-structural improvements to the building. Any amounts utilized by us from the TI Allowance will be subject to an interest accrual at a rate of 8.0% per annum and must be repaid in monthly installments paid concurrently with the base rent. We retain the right at any time during the lease term to prepay all or any portion of the TI Allowance drawn and outstanding without penalty. We currently intend to utilize the entire TI Allowance for improvements to the building over the next six to nine months. We also expect to make additional improvements to the building during this period.

From inception through June 30, 2016, we have primarily financed our operations through sales of equity securities, and, to a lesser extent, debt financings. We expect to continue to incur net losses for the next several years, and may require additional capital through equity and debt financings in order to fund our operations until we achieve a level of revenue adequate to support our cost structure.

In the first quarter of 2016, we entered into a third amendment (the "Third Amendment") to our Term Loan Agreement, as amended by Consent and Amendment Agreement, dated June 20, 2014, Omnibus Amendment Agreement No. 2, dated February 23, 2015 and Amendment No. 3 to Term Loan Agreement, dated January 8, 2016 (as amended, the "Term Loan Agreement") with Capital Royalty Partners II, L.P. and its affiliate funds ("Capital Royalty Partners"). The Third Amendment granted us the right to borrow up to an additional $50.0 million. We borrowed $15.0 million of this amount in January 2016, and the Third Amendment provides us with a one-time option to draw up to an additional $35.0 million in increments of $5.0 million on or before December 31, 2016.

We may not be able to achieve profitability in the future. For additional information about the risks and uncertainties associated with our business, see the section entitled "Risk Factors" in Part II, Item 1A of this Quarterly Report.

Components of Results of Operations

Sales

We offer a family of 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 September 2015. Our products 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 material.

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 recent expansion of our sales, clinical and marketing infrastructure will allow us to engage with more potential customers, their caregivers and healthcare providers on a more frequent basis to promote our products. Our quarterly sales may also fluctuate on a quarterly basis in the future due to a variety of factors, including the impact of:

- 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 size and timing of sales force expansions,

- anticipated and actual regulatory approvals of new products by us or our competitors, and
- our recently announced Technology Upgrade Program and its related financial and accounting impact.

We have experienced and expect to continue to experience sequential growth of product shipments in each quarter from the first quarter to the fourth quarter, and we also expect sequential product shipments from the fourth quarter to the following first quarter to decrease. In 2015, we believe that the timing of the regulatory approval and commercial launch of t:slim G4 contributed to our product shipments being weighted even more heavily towards the fourth quarter of the year. In 2016, we expect the quarterly product shipments distribution to be similar to what we have experienced historically, excluding the impact of the Technology Upgrade Program, due to the combined effect of the increasing productivity of our existing sales force and the newer members of our sales force that were added in the first quarter of 2016, the anticipated contribution from product enhancements, and pump renewal opportunities that will begin in the fourth quarter.

Cost of Sales

We manufacture our pumps and disposable cartridges at our manufacturing facility in San Diego, California. Infusion sets and pump accessories are manufactured by third-party suppliers. Cost of sales includes raw materials, labor costs, manufacturing overhead expenses, product training costs, reserves for expected warranty costs, and scrap and inventory obsolescence. Manufacturing overhead expenses are currently a significant portion of our per-unit costs but continue to decline as our production volumes grow. These manufacturing overhead expenses include expenses relating to quality assurance, manufacturing engineering, material procurement, inventory control, facilities, equipment, information technology and operations supervision and management. We anticipate that our cost of sales will continue to increase as our products continue to gain broader market acceptance.

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 among our pump products that utilize the same core infrastructure. However, we do expect our overall gross margin to fluctuate in future quarterly periods as a result of numerous factors besides those associated with production volumes, such as the Technology Upgrade Program and its related financial and accounting impact, 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 product launches, warranty and training costs, and changes in our manufacturing processes, costs or output, changes in our manufacturing capacity or output as well as the impact of implementing additional automated manufacturing equipment and expanding our manufacturing facilities as we attempt to manufacture our products on a larger scale.

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, business development, regulatory affairs and administrative functions. Other significant SG&A expenses include those incurred for product demonstration samples, commercialization activities associated with new product launches, travel, trade shows, outside legal fees, independent auditor fees, outside consultant fees, insurance premiums, facilities costs and information technology costs. We expect our SG&A expenses to increase as our business expands, including potential future expansions of the number of sales territories in which we operate.

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 R&D 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, 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 initiate and advance our development projects.

Other Income and Expense

Our other income and expense primarily consists of interest expense and amortization of debt discount and debt issuance costs associated with the Term Loan Agreement. At June 30, 2016, there was $45.6 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 2016 as a result of additional borrowings under the Term Loan Agreement (see the section below entitled “Indebtedness”).

Results of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands, except percentages)	2016	2015	2016	2015
Sales	$22,985	$15,706	$43,043	$28,014
Cost of sales	14,809	10,905	27,939	20,406
Gross profit	8,176	4,801	15,104	7,608
Gross margin	36 %	31 %	35 %	27 %
Operating expenses:				
Selling, general and administrative	21,087	19,599	43,084	38,954
Research and development	4,142	3,873	8,310	7,735
Total operating expenses	25,229	23,472	51,394	46,689
Operating loss	(17,053)	(18,671)	(36,290)	(39,081)
Other income (expense), net:				
Interest and other income	107	61	225	160
Interest and other expense	(1,379)	(923)	(2,744)	(1,821)
Total other expense, net	(1,272)	(862)	(2,519)	(1,661)
Net loss	$(18,325)	$(19,533)	$(38,809)	$(40,742)

Comparison of the Three Months Ended June 30, 2016 and 2015

Sales. Sales for the three months ended June 30, 2016 were $23.0 million, representing an increase of 46% compared to sales of $15.7 million for the same period in 2015.

For the three months ended June 30, 2016 and 2015, sales of insulin pumps accounted for 79% and 83% of sales, respectively, while sales of pump-related supplies primarily accounted for the remainder of our sales during those periods. Sales of accessories were not material in either of the reported periods.

The increase in sales during the three months ended June 30, 2016 compared to the same period in 2015 was primarily attributable to a 38% increase in pump shipments from 3,331 in the second quarter of 2015 to 4,582 in the second quarter of 2016. The increase in sales during the three months ended June 30, 2016 compared to the same period in 2015 was also attributable to an increase in sales of pump supplies from our growing installed base.

Sales to distributors accounted for 75% and 78% of our total sales for the three months ended June 30, 2016 and 2015, respectively. The percentage of sales to distributors versus direct 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. We anticipate sales to distributors as a percentage of our total sales to decrease modestly as a result of UnitedHealthcare’s 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.

Cost of Sales and Gross Profit. Our cost of sales for the three months ended June 30, 2016 was $14.8 million, representing an increase of 36% compared to $10.9 million for the same period in 2015. Gross profit for the three months ended June 30, 2016 was $8.2 million and gross margin was 36%, compared to gross profit of $4.8 million and gross margin of 31% for the same period in 2015.

The increase in our gross margin for the three months ended June 30, 2016 from the comparable period in 2015 was primarily due to a decrease in per-unit manufacturing overhead costs of our products, which was driven by increased production volumes and manufacturing efficiencies. We continue to increase our manufacturing operations and costs as we address increasing production volume requirements. Our manufacturing overhead costs have been, and we expect they will continue to be, a significant component of the costs of our products. As a result our manufacturing overhead costs have impacted, and may continue to impact, our gross margins as we attempt to manufacture our products on a larger scale, change our manufacturing processes, change our manufacturing capacity or output, implement additional automated manufacturing equipment and expand our manufacturing facilities. The gross margin was also positively impacted by the percentage of products sold to distributors versus directly to individual customers and the varying levels of reimbursement among third-party payors on our direct business. This increase was partially offset by an increase in sales of pump-related supplies, which generally have lower gross margins than our insulin pumps.

Gross margin for both pumps and cartridges improved during the three months ended June 30, 2016 as compared to the same period in 2015. Our gross margin on the insulin pumps was higher than our gross margin on pump-related supplies for the quarters ended June 30, 2016 and 2015, and is expected to remain higher in the future. Other factors that impact our gross margins include warranty and training costs, new product launch scale-up, and other changes in our manufacturing processes, costs and output.

Selling, General and Administrative Expenses. SG&A expenses increased 8% to $21.1 million for the three months ended June 30, 2016 from $19.6 million for the same period in 2015. The increase in SG&A expenses was primarily associated with the expansion of our commercial operations during the first quarter of 2016. We expanded the number of our sales territories from 60 to 72 during the first quarter of 2016, as well as increased our customer and technical support personnel to service our growing customer base. Territories are maintained by sales representatives and field clinical specialists, and supported by managed care liaisons, additional sales management and other customer support personnel. Employee-related expenses for our sales, general and administrative functions comprise the majority of the SG&A expenses. Employee-related expenses in the second quarter of 2016 increased $1.4 million, including an increase of $1.7 million in salaries, offset by a decrease in non-cash stock-based compensation of $0.2 million.

Research and Development Expenses. R&D expenses increased 7% to $4.1 million for the three months ended June 30, 2016 from $3.9 million for the same period in 2015, primarily associated with an increase in employee-related expenses.

Other Income and Expense. Other expense for the three months ended June 30, 2016 and 2015 was $1.4 million and $0.9 million, respectively. Other expense for both periods was primarily comprised of interest expense associated with the Term Loan Agreement. The increase in expense was due to $15.0 million of additional borrowing under the Third Amendment in 2016. Interest currently accrues at a rate of 11.5% of the outstanding principal balances of $45.6 million and $30.0 million as of June 30, 2016 and June 30, 2015, respectively. Other income for both periods presented was not material.

Comparison of the Six Months Ended June 30, 2016 and 2015

Sales. Sales for the six months ended June 30, 2016 were $43.0 million, representing an increase of 54% compared to sales of $28.0 million for the same period in 2015.

For the six months ended June 30, 2016 and 2015, sales of insulin pumps accounted for 80% and 82% of sales, respectively, while sales of pump-related supplies primarily accounted for the remainder of our sales during those periods. Sales of accessories were not material in either of the reported periods.

The increase in sales during the six months ended June 30, 2016 compared to the same period in 2015 was primarily attributable to a 48% increase in pump shipments from 5,818 in the first six months of 2015 to 8,624 in the first six months of 2016. During the first six months of 2016, we expanded from 60 to 72 sales territories. The increase in sales during the six months ended June 30, 2016 compared to the same period in 2015 was also attributable to an increase in sales of pump supplies from our growing installed base.

Sales to distributors accounted for 76% and 77% of our total sales for the six months ended June 30, 2016 and 2015, respectively. The mix of sales to distributors versus direct customers is principally determined by whether or not we have a contractual arrangement with the underlying third-party insurance payor.

Cost of Sales and Gross Profit. Our cost of sales for the six months ended June 30, 2016 was $27.9 million, representing an increase of 37% compared to $20.4 million for the same period in 2015. Gross profit for the six months ended June 30, 2016 was $15.1 million and gross margin was 35% compared to gross profit of $7.6 million and gross margin of 27% for the same period in 2015.

The increase in our gross margin for the six months ended June 30, 2016 from the comparable period in 2015, was primarily due to a decrease in per-unit manufacturing overhead costs of our products, which was driven by increased production volumes and manufacturing efficiencies. The gross margin was also positively impacted by the percentage of products sold to distributors versus directly to individual customers and the varying levels of reimbursement among third-party payors on our direct business. This increase was partially offset 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 11% to $43.1 million for the six months ended June 30, 2016 from $39.0 million for the same period in 2015. The increase in SG&A expenses was primarily associated with the expansion of our commercial operations during the first quarter of 2016. Employee-related expenses for our sales, general and administrative functions comprise the majority of the SG&A expenses. Such employee-related expenses increased $3.2 million in the six months ended June 30, 2016 as compared to the same period in 2015, including an increase of $3.4 million in salaries and $0.7 million in sales commissions and bonuses,

offset by a decrease in non-cash stock-based compensation of $0.9 million. SG&A expenses also increased $0.9 million associated with outside services, marketing and promotional activities, tradeshows and travel expenses.

Research and Development Expenses. R&D expenses increased 7% to $8.3 million for the six months ended June 30, 2016 from $7.7 million for the same period in 2015, primarily associated with an increase in employee-related expenses and expenses for outside services.

Other Income and Expense. Other expense for the six months ended June 30, 2016 and 2015 was $2.7 million and $1.8 million, respectively. Other expense for both periods was primarily comprised of interest expense associated with the Term Loan Agreement. The increase in expense was due to $15.0 million of additional borrowing under the Third Amendment in the six months ended June 30, 2016. Interest currently accrues at a rate of 11.5% of the outstanding principal balances of $45.6 million and $30.2 million as of June 30, 2016 and December 31, 2015, respectively. Other income for both periods presented was not material.

Liquidity and Capital Resources

At June 30, 2016, we had $56.3 million in cash, cash equivalents and short-term investments, which included $2.0 million of restricted cash. We believe that our cash on hand, cash generated from operations, cash available under the Term Loan Agreement, proceeds from the exercise of options and warrants, and proceeds from employee contributions for the purchase of our common stock through our ESPP will be sufficient to satisfy our liquidity requirements for at least the next 12 months. We expect that 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. We have utilized, and may continue to utilize, debt arrangements with debt providers and financial institutions to finance our operations. Factors such as interest rates, repayment terms and available cash will impact our decision regarding whether to continue to utilize debt arrangements as a source of cash, including whether to draw additional amounts available to us under the Term Loan Agreement. In November 2013, we completed an initial public offering of common stock that resulted in net proceeds of approximately $125.0 million, and in the first quarter of 2015 we completed a public offering of common stock that resulted in net proceeds of approximately $64.9 million. In the future, we may give consideration to additional public offerings of equity securities as a source of financing. In December 2014, we filed a registration statement on Form S-3 with the Securities and Exchange Commission (“SEC”), which was declared effective on December 19, 2014. Under this shelf registration statement, we may from time to time offer and sell any combination of common stock, preferred stock, warrants or units in one or more offerings.

Historically, our principal sources of cash have included private placements and public offerings of equity securities, debt arrangements, and cash generated from operations. 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, an 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.

The following table shows a summary of our cash flows for the six months ended June 30, 2016 and 2015:

	Six Months Ended June 30, 2016	
(in thousands)	2016	2015
Net cash provided by (used in):		
Operating activities	$(29,437)	$(34,180)
Investing activities	45	(17,968)
Financing activities	16,554	66,893
Total	$(12,838)	$14,745

Operating activities. Net cash used in operating activities was $29.4 million for the six months ended June 30, 2016, compared to $34.2 million for the same period in 2015. The change in net cash used in operating activities was

primarily associated with a decrease in our operating loss and changes in working capital. The changes in working capital were primarily due to improvement in cash collection from accounts receivable and changes in accounts payable, employee-related liabilities and other current liabilities, and offset by an increase in inventory to meet higher production volumes, including those associated with new products, and an increase in prepaid expenses.

Investing activities. Net cash provided by investing activities was $45,000 for the six months ended June 30, 2016, which was primarily related to the purchase of $22.7 million of short-term investments and $4.0 million of property and equipment, offset by proceeds from maturities of short-term investments of $26.8 million. Net cash used in investing activities was $18.0 million for the six months ended June 30, 2015, which was primarily related to the net purchase of $59.0 million in short-term investments and $2.4 million of property and equipment, offset by proceeds from maturities of short-term investments of $43.5 million.

Financing activities. Net cash provided by financing activities was $16.6 million for the six months ended June 30, 2016, which was primarily the result of net proceeds in the amount of $15.0 million in connection with the Third Amendment and $1.6 million in proceeds from the issuance of common stock through our ESPP, as well as the exercise of outstanding stock options and warrants. Net cash provided by financing activities was $66.9 million for the six months ended June 30, 2015, which was primarily the result of the net proceeds from a public offering of our common stock in the amount of $64.9 million and $2.0 million in proceeds from the issuance of common stock through 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. For example, our cash inflow and outflow may be impacted by the following:

- our ability to generate sales and the timing of those sales from period to period;

- fluctuations in gross margins and operating margins;
- fluctuations in working capital; and
- our decision whether to draw additional amounts available under the Term Loan Agreement.

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;
- costs associated with the Technology Upgrade Program;
- improvements in our manufacturing capacity and efficiency;
- new research and product development efforts;
- payment of interest due under the Term Loan Agreement;
- the acquisition of equipment and other fixed assets;
- facilities expansion needs; 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. If cash generated from operations is insufficient to satisfy our working capital and capital expenditure requirements, we may be required to sell additional equity or debt securities or obtain additional credit facilities. There can be no assurance that equity or debt financing will be available on satisfactory terms, or at all. Further, any additional equity financing may be dilutive to stockholders, and debt financing, if available, may include restrictive covenants.

Indebtedness

Term Loan Agreement

At December 31, 2015, we had $30.2 million aggregate borrowings outstanding under the Term Loan Agreement. In January 2016, we entered into a third amendment to our Term Loan Agreement, which allowed us to borrow up to an additional $50.0 million. We borrowed $15.0 million in January 2016, and the Third Amendment provides us with a one-time option to draw up to an additional $35.0 million in increments of $5.0 million on or before December 31, 2016.

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 at the end of the term of the loan which is March 31, 2020. The Term Loan Agreement provided for prepayment fees in an amount equal to 1.0% of the outstanding balance of the loan if the loan is repaid prior to March 31, 2017, after which there is no prepayment fee.

We had elected to pay interest in cash at a rate of 11.5% per annum through September 30, 2015. For the six months ended June 30, 2016 and the three months ended December 31, 2015, we elected to pay interest in cash at a rate of 9.5% per annum and to have a rate of 2.0% per annum added to the principal of the loan. As a result, $442,000 and $153,000 was added to the principal of the loan for the six months ended June 30, 2016 and the three months ended December 31, 2015, respectively. As of June 30, 2016, we had $45.6 million of aggregate borrowings outstanding under the Term Loan Agreement.

The loan is collateralized by all of our assets. The Term Loan Agreement also imposes various affirmative and negative covenants on us. The principal financial covenants require that we attain minimum annual revenues of $65.0 million in 2016, $80.0 million in 2017 and $95.0 million each year thereafter until the end of the term of the loan. At June 30, 2016, we were in compliance with all of the covenants in the Term Loan Agreement.

Under the Third Amendment, we have 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 we make a voluntary pre-payment of the loan, a financing fee equal to three percent (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.

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 our Annual Report on Form 10-K for the year ended December 31, 2015.

Off-Balance Sheet Arrangements

As of June 30, 2016, 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 June 30, 2016, 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 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 June 30, 2016, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2016.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the quarter ended June 30, 2016 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 may be involved in various disputes and litigation matters that arise in the ordinary course of business. We are currently not a party to any material legal proceedings. There can be no assurance that existing or future legal proceedings arising in the ordinary course of business or otherwise will not have a material adverse effect on our business, financial position, results of operations or cash flows.

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 our Annual Report on Form 10-K for the year ended December 31, 2015.

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 June 30, 2016, we had an accumulated deficit of $359.9 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 research and development of our products, the scaling of manufacturing operations and our commercial organization, the commercial launch of our products, and the assembly of a management team to manage our business.

We began commercial sales of our first commercial product, the t:slim pump, in the third quarter of 2012. We began commercial sales of the t:flex pump in the second quarter of 2015 and the t:slim G4 pump in the third quarter of 2015. 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, 2015 and 2014, our gross profit was $26.6 million and $15.2 million, respectively. For the three months ended June 30, 2016 and 2015, our gross profit was $8.2 million and $4.8 million, respectively. However, although we have achieved a positive overall gross margin, we still operate at a substantial 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, grow our sales, clinical and marketing infrastructure to increase sales of our products, fund ongoing research and development activities, expand our manufacturing capabilities, and obtain regulatory clearance or approval to commercialize our products currently under development. We expect our expenses to increase significantly as we pursue these objectives. The extent of our future operating losses and the timing of profitability are highly uncertain, especially given that we intend to launch several new products and product features, and offer a Technology Upgrade Program, which makes forecasting our sales more difficult. 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.

The implementation of our Technology Update Program may result in unanticipated difficulties or costs, which may harm our financial condition or operating results; the Update Program will result in accounting complexities that may be difficult for investors to understand and may lead to confusion when comparing our historical and future financial results. *

In July 2016, we announced the implementation of a Technology Upgrade Program that will allow eligible t:slim and t:slim G4 Pump customers the ability to upgrade from their existing pump to a t:slim X2 Pump, subject to the conditions specified in the Upgrade Program. The Upgrade Program is being offered to provide our existing customers the ability to upgrade to the features and capabilities of the t:slim X2 Pump once it is commercially launched. However, we do not have any experience implementing exchange programs of this type and we may encounter unexpected difficulties or costs in administering or fulfilling our obligations under the Upgrade Program.

If we incur unexpected difficulties or costs in administering the Upgrade Program, or if we do not derive the anticipated benefits to our business from offering the Upgrade Program to our customers, it could have a material adverse effect on our financial condition and operating results.

Furthermore, the implementation of the Upgrade Program will result in a number of accounting complexities that will make comparisons of our future and historical financial results more difficult. In particular, United States generally accepted accounting principles ("GAAP") prevent the Company from recognizing, at the time of sale, the full amount of the revenue and cost of goods sold associated with the sale of t:slim and t:slim G4 pumps made to eligible customers during the Upgrade Program. Instead, depending on the type of pump sold, the Company will be required to defer some or all of the revenues and costs of goods sold until a later date, which will generally be the earlier of when our obligations under the Upgrade Program are satisfied or when the Upgrade Program expires. The amount and timing of the deferred revenues and cost of goods sold will depend on multiple factors that are based on future events that are difficult to estimate or predict. In addition, because we have not offered a similar exchange program in the past, we do not have the experience necessary to predict some of these factors. 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, with any level of certainty.

Despite our efforts to explain the anticipated accounting treatment, it is possible that investors or analysts will view the accounting treatment or the resulting impact on our GAAP financial results negatively, or it may lead to 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 Upgrade Program generally, may cause investors to avoid purchasing our common stock until the impact of the Upgrade Program is better understood or the Company financial results and trends are more predictable, which also may adversely impact our stock price. Finally, while the anticipated accounting treatment for the Upgrade Program as described above represents our current expectations based on information currently available, it is preliminary and subject to change in the future.

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. Due to our existing production volumes relative to our potential production capacity, manufacturing costs are currently a significant portion of our per-unit costs. Our manufacturing costs include raw material procurement costs, labor costs, product-training expenses and expected warranty expenses. They also include 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 manufacturing costs, 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 manufacturing 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.

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 expected per unit costs. If we are unable to effectively manage our overall manufacturing 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 and financial condition.

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 commercial revenue from the sale of our family of insulin pump products, which include our t:slim, t:flex and t:slim G4 products.

Sales of our insulin pumps may be negatively impacted by many factors, including:

- problems arising from the expansion of our manufacturing capabilities, or destruction, loss, or temporary shutdown of our manufacturing facility;
- changes in reimbursement rates or policies relating to insulin pumps or similar products or technologies by third-party payors;
- our inability to enter into contracts with third-party payors on a timely basis and on acceptable terms;

- 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;

- the failure of our Tandem Device Updater to accurately and timely provide customers with remote access to new product features as anticipated;

- the potential that other technological breakthroughs for the monitoring, treatment or prevention of diabetes may render our insulin pump products obsolete or less desirable; and

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

In addition, sales of any of our current or future insulin pump products with integration of CGM, such as the t:slim G4, are subject to the continuation of our applicable agreements with DexCom, which are subject to termination by DexCom, with or without cause, on relatively short notice.

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 and negatively impact our ability to successfully launch future products currently under development.

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 family of insulin pump products, which include t:slim, t:flex and t:slim G4, achieving and maintaining market acceptance. In order for us to sell our products to people with insulin-dependent diabetes, we must convince them, their caregivers and healthcare providers that it is 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, as to 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 wide acceptance among people with insulin-dependent diabetes, their caregivers, insulin-prescribing healthcare providers, third-party payors and key opinion leaders in the diabetes treatment community;

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

perceived risks 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; and

results of clinical studies relating to t:slim, t:flex, t:slim G4 or similar competitive products.

In addition, t:slim, t:flex and t:slim G4 may be perceived by people with insulin-dependent diabetes, their caregivers or healthcare providers to be more complicated, less reliable or less effective than traditional insulin therapies, including MDI, and people may be unwilling to change their current treatment regimens.

Moreover, we believe that healthcare providers tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products and the uncertainty of third-party reimbursement. Accordingly, healthcare providers may not recommend our products until there is sufficient evidence to convince them to alter the treatment methods they typically recommend, such as receiving recommendations from prominent healthcare providers or other key opinion leaders in the diabetes treatment community that our products are effective in providing insulin therapy. Additionally, payors may have more stringent requirements for reimbursement.

Further, 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, 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 third quarter of 2015 there were consumers interested in purchasing one of our insulin pump products who may have delayed the purchase decision in anticipation of the release of t:slim G4. It is also possible that consumers interested in purchasing any of our future products currently in development, such as the t:slim X2, 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 projections, we may fail to meet our strategic objectives, and our business, financial condition and operating results could be materially and adversely affected.

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

We have derived nearly all of our revenue from sales of t:slim, t:flex and t:slim G4 pumps and associated supplies, and expect to continue to do so until we are able to commercialize our other products that are currently under development. 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. Because we only recently initiated commercial sales of t:flex and t:slim G4, there remains some uncertainty regarding the coverage that third-party payors will offer for these products, particularly for individuals with type 2 diabetes where coverage requirements may necessitate additional laboratory tests or other information to support a determination of medical necessity. 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.

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, as guidelines in setting their coverage and reimbursement policies. Medicare periodically reviews its reimbursement practices for diabetes-related products. Medicare 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, Medicare has also initiated a competitive bidding process for insulin pumps in limited geographies. 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 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 156 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 addition, 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 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 or technologies, or other activities of industry participants. We expect our products will compete directly with a number of traditional insulin pumps as well as other methods for the treatment of diabetes. In particular, we expect that the competitive landscape for t:flex, t:slim G4 and our products under development will be similar to that of t:slim.

Many of our existing and potential 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. Other significant insulin pump suppliers in the United States include Animas Corporation, a division of Johnson & Johnson, and Insulet Corporation. There are also newer companies entering the field.

Many of these more established competitors enjoy several competitive advantages over us, including:

- greater financial and human resources for sales and marketing, and product development;
- established relationships with healthcare providers and third-party payors;
- established reputation and name recognition among healthcare providers and other key opinion leaders in the diabetes industry;
- in some cases, an established base of long-time 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 also offer products that include features that we do not currently offer. For instance, Medtronic currently offers a traditional insulin pump that is integrated with a CGM system with a threshold suspend feature, and Insulet offers an insulin pump with a tubeless delivery system that does not utilize an infusion set. Medtronic also recently announced that it has submitted for FDA approval of a new insulin pump product with additional functionality and a new CGM system. For these and other reasons, we may not be able to compete successfully against our current or potential future competitors. As a result, we may fail to meet our strategic objectives and forecasted budget, and our business, financial condition and operating results could be materially and adversely affected.

Competitive products or other technological breakthroughs for the monitoring, treatment or prevention of diabetes or technological developments 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, 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 technological or treatment advancements could occur in the future 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, the entry of multiple new products has led some of our competitors to employ 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 own 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 continual 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.

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. For example, we do not have significant experience training new customers on the use of continuous glucose monitoring, which we are required to provide to customers in connection with the commercialization of t:slim G4. As a result, we may face unexpected challenges marketing and selling t:slim G4 and any future products that utilize continuous glucose monitoring. 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.

We expect to derive nearly all of our revenue from the sale of t:slim, t:flex, t:slim G4 and pump-related supplies unless and until we receive regulatory clearance or approval for other products currently in development. As a result, our financial condition and operating results are and will continue to be highly dependent on the ability of our sales representatives to adequately promote, market and sell our current family of insulin pumps, 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 expand our sales, marketing and clinical infrastructure effectively and on a timely basis, we may fail to increase our sales to meet our forecasts.*

A key element of our business strategy is the continued expansion of our sales, clinical and marketing infrastructure to drive adoption of our products, which includes our team of diabetes educators that trains new customers on the use of our products. We have rapidly increased the number of sales, marketing and clinical personnel employed by us since the initial commercial launch of t:slim in 2012. However, we have faced considerable challenges in growing and managing our sales, marketing and clinical force over the past 12-18 months, 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 sales, marketing and clinical infrastructure and work to motivate and retain the individuals who make up those networks. These challenges may be even greater in light of our plans to further expand our commercial organization during 2016, especially because newly hired sales, clinical and marketing representatives require training and take time to achieve full productivity. Moreover, the expansion of our sales force has disrupted, and we expect that it will continue to disrupt the productivity of our existing sales representatives. Unexpected turnover, especially during a period of anticipated expansion, 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, we may not be able to successfully train new customers on the use of our products, which could delay new sales and harm our reputation.

We expect that the management and future expansion of our sales, marketing and clinical personnel will continue to place significant burdens on our management team. If we are unable to retain and expand our sales, marketing and clinical capabilities 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 own. 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, 2015, sales to approximately 40 independent distributors represented approximately 77% of our sales. While our goal is to reduce the percentage of our sales to independent distributors over time as we enter into contracts with additional third-party payors, we believe 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 on a direct basis. Our dependence upon independent distributors could also increase if customers prefer to purchase all of their diabetes supplies through a single source, instead of purchasing pump-related products through us and other diabetes supplies through other suppliers. None of our independent distributors 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.

Some of our independent distributors account for a significant portion of our sales volume. For the year ended December 31, 2015, our two largest independent distributors comprised approximately 35% of our sales. If any of our key independent distributors were to cease to distribute our products, 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 these third parties on a timely basis or on acceptable terms, or these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our 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.

We are increasingly dependent on clinical investigators and clinical sites to enroll patients in our current and anticipated clinical trials and other third parties to manage such trials and to perform related data collection and analysis, and, as a result, we may face costs and delays that are outside of our control. *

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

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 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. 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. 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 rapidly. 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. Moreover, even if our market research has allowed us to better understand the features 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 and may face difficulties 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, especially with respect to the impact of t:flex and t:slim G4 on our mix of product sales and our overall growth rate. 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 companies that develop and sell medical devices. These risks include our ability to:

- implement and execute our business strategy;

expand 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;

manage expanding operations, including complying with a broad range of legal requirements within a highly regulated industry;

expand our manufacturing capabilities, including increasing production of current 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 commercialize proposed products and enhance our existing 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 and 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;
- our failure to increase production of products to meet demand;
- the challenge of implementing and maintaining acceptable quality systems while experiencing rapid growth;
- our inability to modify production lines to enable us to efficiently produce future products or implement changes in current products in response to regulatory requirements;
- our ability to manufacture multiple products simultaneously while utilizing common manufacturing equipment;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner; 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 derive the anticipated improvements from these investments. We recently entered into a new lease agreement for additional facilities to consolidate substantially all of our manufacturing, warehousing and other operational needs, and any transition of our current manufacturing, warehousing and other operations to a new facility is subject to additional risk and uncertainty. If we fail to increase our production capacity efficiently while also maintaining quality requirements, our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline.

In addition, although we expect some of our products in 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. It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable.

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

We 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. Increases in 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 most 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 products, and our suppliers have no obligation to manufacture for us or sell to us any given quantity of products. As a result, our ability to purchase adequate quantities of our products may be limited. Additionally, our suppliers may encounter problems that limit their ability to manufacture 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.

We generally use a small number of suppliers for our products. Depending on a limited number of suppliers exposes us to risks, including limited control over pricing, availability, quality and delivery schedules. Moreover, due to the recent commercialization of our products and the limited amount of our sales to date, 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 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. It 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 result in a requirement to seek 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.

We currently operate primarily at a single location comprised of five buildings, and any disruption at this location could adversely affect our business and operating results.

Our principal offices are presently located in five buildings in San Diego, California. Substantially all of our operations are presently conducted at this location, 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 is held at this location. 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 or finished goods, cause substantial delays in our operations, result in the loss of key information, and cause us to incur additional expenses. Our insurance may not cover our losses in any particular case. In addition, 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.

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 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 consumers, their caregivers, healthcare providers or third-party payors who reimburse consumers for our products. The success of any proposed product offerings will depend on numerous factors, including our ability to:

- identify the product features 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 proposed 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 developing products that incorporate features requested by consumers, 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 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 commercial launch, 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.

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 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 received FDA approval under a PMA. However, there are no published studies to evaluate the safety or effectiveness of t:slim G4.

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.

Moreover, we monitor and investigate incoming customer complaints on an ongoing basis, particularly following the launch of new products or changes to our existing products. Changes to our existing products may include changes to hardware or software, including remote software updates made using our Tandem Device Updater, or changes to manufacturing methods or procedures. 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, 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 or any future collaborators devote to our collaborators' or our future products. Disputes between our collaborators and us 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 a Development and Commercialization Agreement with DexCom, which provides us a non-exclusive license to integrate the DexCom G4 PLATINUM CGM System with t:slim G4 during the term of the agreement. This agreement currently runs until January 4, 2018, with automatic one-year renewals. The license granted covers the United States and other territories may be added from time to time. Under certain circumstances, the agreement may be terminated by either party without cause or on short notice. Termination of this agreement could require us to redesign t:slim G4 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 in the availability of the product to our customers.

If there are significant disruptions in our information technology systems, our business, financial condition and operating results could be adversely affected.*

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage sales and marketing data, accounting and financial functions, manufacturing and quality records, inventory management, product development tasks, research and development data, customer service and technical support functions. Our information technology systems, including those that support t:connect, our cloud-based data management application, and 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 in development contain software, which could be subject to computer virus or hacker attacks or other failures. As a result of the recent FDA clearance of our Tandem Device Updater, which enables customers to remotely update the 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 updated software for our pumps, which we anticipate will allow customers remote access to new and enhanced features, including future continuous glucose monitoring integration and artificial pancreas pump algorithms. 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 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, 2014 and December 31, 2015 our employee base increased approximately 10% and we expect to continue to experience growth of our employee base during 2016. In addition, during late 2015 and early 2016 we experienced turnover among key employees in our sales, marketing and clinical functions, including the recent hiring of a new Chief Commercial Officer. Our failure to manage growth effectively could cause us to misallocate management or financial resources, and result in losses or weaknesses in our infrastructure, which could materially adversely affect our business. Additionally, our anticipated growth 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. 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.

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 the 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 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 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. 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

Our future capital needs are uncertain and we may need to raise additional funds in the future, and these funds may not be available on acceptable terms or at all. *

At June 30, 2016, we had $56.3 million in cash, cash equivalents and short-term investments, which included $2.0 million of restricted cash. We believe that our cash on hand, cash available under the Term Loan Agreement, cash generated from operations, and cash proceeds from the exercise of warrants and options will be sufficient to satisfy our liquidity requirements for at least the next 12 months. However, the continued growth of our business, including the expansion of our sales, clinical and marketing infrastructure, research and development activities, and manufacturing capabilities, will continue to increase our expenses. In addition, the amount of our future product sales is difficult to predict and actual sales may not be in line with our forecasts. As a result, we may seek additional funds in the future. Our future capital requirements will depend on many factors, including:

- the revenue generated by sales of our family of insulin pump products, and any other future products that we may develop and commercialize;
- the costs associated with maintaining and expanding our sales and marketing infrastructure;
- the expenses we incur in maintaining our manufacturing facility and adding additional manufacturing equipment and capacity;
- the cost associated with developing and commercializing our proposed products or technologies, including any costs associated with the Technology Upgrade Program;
- the cost of obtaining and maintaining regulatory clearance or approval for our current or future products;
- the cost of ongoing compliance with legal and regulatory requirements;
- expenses we incur in connection with potential litigation or governmental investigations;

anticipated or unanticipated capital expenditures; and

unanticipated general and administrative expenses.

As a result of these and other factors, we do not know the extent to which we may be required to raise additional capital. We may in the future seek additional capital from public or private offerings of our capital stock, we may elect to borrow additional amounts under the Term Loan Agreement under new credit lines or other sources. In particular, we have an effective shelf registration statement on file with the SEC, under which we may offer to sell equity securities. 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 expand our sales and marketing infrastructure, enhance our current products or develop new products, take advantage of future opportunities, or respond to competitive pressures, changes in supplier relationships, or unanticipated changes in customer demand. Any of these events could adversely affect our ability to achieve our strategic objectives, which could have a material adverse effect on our business, financial condition and operating results.

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

There has been and may continue to be meaningful variability in our operating results from quarter to quarter, as well as within each quarter, especially around the time of anticipated new product introductions. Our operating results, and the variability of these operating results, will be affected by numerous factors, including:

- our ability to increase sales of our currently available insulin pump products 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 impact of our Technology Upgrade Program;
- the pricing of our products and competitive products, including the use of discounts, rebates or other financial incentives by our competitors;
- the effect of third-party coverage and reimbursement policies;
- our ability to establish and grow an effective sales, clinical and marketing 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 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 the t:slim X2 pump, there will be an increasing number of customers anticipating its availability and they may delay their purchasing decisions until they could include the t:slim X2 in their decision-making process.

In addition, we will continue to increase our operating expenses as we expand our business. Accordingly, we may experience substantial variability in our operating results from quarter to quarter, including anticipated or unanticipated quarterly losses. If our quarterly or annual operating results fall below the expectation of investors or securities analysts, the price of our common stock could decline substantially. Further, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. 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 may not be able to generate sufficient cash to service our indebtedness, which currently consists of our credit facility with Capital Royalty Partners. *

At December 31, 2015, we had $30.2 million aggregate borrowings outstanding under the Term Loan Agreement. In January 2016, we entered into a third amendment to our Term Loan Agreement, which allowed us to borrow up to an additional $50.0 million. We borrowed $15.0 million in January 2016, and the Third Amendment provides us with a one-time option to draw up to an additional $35.0 million in increments of $5.0 million on or before December 31, 2016. 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 assets or operations, seek additional capital, 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. In addition, in the event of our breach of the Term Loan Agreement, we may be required to repay any outstanding amounts earlier than anticipated.

The Term Loan Agreement contains restrictive and financial covenants that may limit our operating flexibility.

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 therefore may not be able to engage in any of the foregoing transactions unless we obtain the consent of the lenders or terminate the applicable 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 our 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 a given agreement.

Risks Related to our Intellectual Property and Potential Litigation

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

We rely primarily on patent, trademark and trade secret laws, as well as confidentiality and non-disclosure agreements, to protect our proprietary technologies. As of June 30, 2016, our patent portfolio consisted of approximately 45 issued U.S. patents and 50 pending U.S. patent applications. Of these, our issued U.S. patents expire

between approximately 2021 and 2034. We are also seeking patent protection for our proprietary technology in other countries throughout the world. In addition, we own two pending U.S. trademark applications as well as 22 trademark registrations, including nine 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 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 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 desire 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, we may provoke third parties to assert claims 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 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 be 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 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. 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) clearance 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 received 510(k) clearance for modifications to t:slim and its associated cartridge during 2014 and we are pursuing, and expect to continue to pursue, 510(k) clearance for additional modifications to t:slim and t:flex in the future. For instance, in July 2016 we received 510(k) clearance to reduce the age in our indications for use of the t:slim to age six. Also in July 2016, we received 510(k) clearance for the first use of our Tandem Device Updater. 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. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain PMA process.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

we may not be able 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

the manufacturing process or facilities we use may not 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, 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 or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and operating results.

Further, we may evaluate international expansion opportunities in the future. 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 comply any such requirements, our international expansion and business could be significantly harmed.

Modifications to our products may require new 510(k) clearances or pre-market approvals, 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 previously 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 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 our third-party suppliers or we 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.

Our third-party suppliers and we 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 our suppliers or we have significant non-compliance issues or if any corrective action plan that our suppliers or we 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. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device 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, which could impair

our ability to produce our products in a cost-effective and timely manner.

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 Law, 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;

the federal HIPAA of 1996, which created federal criminal laws 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. A person 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 the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of those prohibitions. Any violations 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, especially in light of the lack of applicable precedent and regulations. 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 off-label promotion of our products.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of 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. Product liability claims are expensive to defend and could result in substantial damage awards against us and harm our reputation.

Legislative or regulatory healthcare reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of our products.

Recent political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. 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 contain or reduce the cost of healthcare. This legislation and regulation may result in decreased reimbursement for medical devices, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices. This could harm our ability to market our products and generate sales.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our products. Delays in receipt of or failure to receive regulatory clearances or approvals for our proposed products would have a material adverse effect on our business, financial condition and operating results.

Federal and state governments in the United States have enacted legislation to overhaul the nation’s healthcare system. While the goal of healthcare reform is to expand coverage to more individuals, it also involves increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. The PPACA substantially changes 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 industries. Among other things, the PPACA:

- establishes a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research;
- implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- creates an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. Most recently, on August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation’s automatic reduction to several government programs. This includes aggregate

reductions to Medicare payments to providers of up to 2% per fiscal year which commenced in 2013. The uncertainties regarding the ultimate features of the PPACA and other healthcare reform initiatives and their enactment and implementation may have an adverse effect on our customers' purchasing decisions regarding our products. In the coming years, 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, or the PPACA, may have on our business and operations, and any of these impacts may be adverse on our operating results and financial condition.

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

The PPACA imposes, among other things, an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States beginning in 2013. Under these provisions, the Congressional Research Service predicts that the total cost to the medical device industry may be up to $20 billion over the next decade. We do not believe that our current products are currently subject to this tax based on the retail exemption under applicable Treasury Regulations. However, the availability of this exemption is subject to interpretation by the IRS, and the IRS may disagree with our analysis. In addition, future products that we manufacture, produce or import may be subject to this tax. 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

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

Based on an aggregate of 30,613,173 shares of our common stock outstanding as of June 30, 2016, our executive officers and directors, and their affiliates owned, in the aggregate, approximately 39% 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 in 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, 2015, we had federal net operating loss, or NOL, carryforwards of approximately $226.3 million, not considering the limitation discussed below. The federal tax loss carryforwards begin to expire in 2026, unless previously utilized. In general, if there is an “ownership change” with respect to our company, as defined under Section 382 of the Internal Revenue Code of 1986, as amended, which we refer to as 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 determined that it is more likely than not that an ownership change occurred in March 2015, we have not completed an update of our Section 382 analysis subsequent to December 31, 2013. When this analysis is finalized, we will reassess the amount of net operating losses and credits subject to limitation under Section 382.We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. Accordingly, if we earn net taxable income, our ability to use net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increases in our future tax liabilities.

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 the Term Loan Agreement, 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 shares and you may lose the entire amount of the investment.

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

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

The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Recent legislation permits "emerging growth companies" to implement many of these requirements over a period of up to five years after becoming subject to the requirements. 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.

New 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.

On August 22, 2012, the SEC adopted a new 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 are currently investigating 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 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 we will rely 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.

Pursuant to 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 for so long as we are an “emerging growth company.”

Under existing SEC rules and regulations, we will be required to disclose changes made in our internal control over financial reporting on a quarterly basis and management will be required to assess the effectiveness of our controls annually. However, 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(b) of the Sarbanes-Oxley Act until we are no longer an “emerging growth company.” We could be an “emerging growth company” for up to five years from our November 2013 initial public offering.

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 in 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.

Prior to our initial public offering in November 2013, there was no public market for our common stock. The trading price of our common stock is likely to be volatile for the foreseeable future. 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, including the financial and accounting impact of the Technology Upgrade Program;
- our actual or perceived need for additional capital to fund our operations;
- perceptions about the market acceptance of our products and the recognition of our brand;
- overall performance of the equity markets;
- introduction of proposed products, or announcements of significant contracts, licenses or acquisitions, by us or our competitors;
- 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 our share price.

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. We had outstanding 30,613,173 shares of common stock as of June 30, 2016, of which approximately 11,981,965 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 June 30, 2016, we had outstanding options to purchase 6,774,815 shares of common stock and warrants to purchase 990,031 shares of common stock that, if exercised, will result in these additional shares becoming available for sale. As of June 30, 2016, there are also an aggregate of 2,578,711 shares of our common stock reserved for future grant or issuance under the 2013 Plan and the ESPP.

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 sold 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 also may issue our securities if we need to raise additional capital. 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.

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*	Employee Offer Letter, dated January 12, 2016, by and between Tandem Diabetes Care, Inc. and Brian B. Hansen.	8-K	001-36189	2-Feb-16	10.1	
10.2*	Employment Severance Agreement, dated February 1, 2016, by and between Tandem Diabetes Care, Inc. and Brian B. Hansen.	8-K	001-36189	2-Feb-16	10.2	
10.3	Lease Agreement, dated June 30, 2016, by and between Tandem Diabetes Care, Inc. and ARE-SD REGION NO. 36, LLC.					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

* Indicates management contract or compensatory plan.

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

SIGNATURES

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

Tandem Diabetes Care, Inc.

Dated: July 28, 2016

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)