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.

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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;