TANDEM DIABETES CARE INC
Form 10-Q
November 06, 2014

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 September 30, 2014

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 (State or other jurisdiction of incorporation or organization)	20-4327508 (I.R.S. Employer Identification No.)
11045 Roselle Street	
San Diego, California (Address of principal executive offices)	92121 (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 ¨
Non-accelerated filer x (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 October 30, 2014, there were 23,500,687 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

	September 30, 2014 (Unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$35,558,073	$124,385,137
Restricted cash	2,000,000	2,050,000
Short-term investments	44,318,806	5,095,331
Accounts receivable, net	5,842,849	5,298,502
Inventory	11,891,586	10,330,156
Prepaid and other current assets	1,438,282	1,830,056
Total current assets	101,049,596	148,989,182
Property and equipment, net	12,344,942	9,885,985
Patents, net	2,459,230	2,697,220
Other long term assets	710,931	642,746
Total assets	$116,564,699	$162,215,133
Liabilities and stockholders’ equity		
Current liabilities:		
Accounts payable	$3,046,800	$2,352,037
Accrued expense	1,190,483	1,873,565
Employee-related liabilities	8,367,716	5,876,011
Deferred revenue	638,143	411,423
Other current liabilities	2,412,812	4,086,196
Total current liabilities	15,655,954	14,599,232
Notes payable—long-term	29,415,563	29,396,571
Deferred rent—long-term	2,853,814	1,886,508
Other long-term liabilities	1,156,092	795,640
Total liabilities	49,081,423	46,677,951
Commitments and contingencies		
Stockholders’ equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized, 23,491,770 and 22,925,614 shares issued and outstanding at September 30, 2014 (unaudited) and December 31, 2013, respectively	23,492	22,926
Additional paid-in capital	297,689,896	284,705,251
Accumulated other comprehensive income	18,811	—
Accumulated deficit	(230,248,923)	(169,190,995)

Total stockholders’ equity	67,483,276	115,537,182
Total liabilities and stockholders’ equity	$116,564,699	$162,215,133

See accompanying notes to condensed financial statements.

TANDEM DIABETES CARE, INC.

CONDENSED STATEMENTS OF OPERATIONS and comprehensive loss

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Sales	$13,513,716	$7,776,150	$31,833,824	$18,762,301
Cost of sales	9,116,570	5,243,288	23,121,269	13,783,155
Gross profit	4,397,146	2,532,862	8,712,555	4,979,146
Operating expenses:				
Selling, general and administrative	18,894,758	12,008,799	55,003,966	30,217,184
Research and development	4,508,004	2,651,580	11,869,567	7,732,818
Total operating expenses	23,402,762	14,660,379	66,873,533	37,950,002
Operating loss	(19,005,616)	(12,127,517)	(58,160,978)	(32,970,856)
Other income (expense), net				
Interest and other income	29,991	151	79,275	611
Interest and other expense	(923,771)	(1,205,697)	(2,976,225)	(3,543,568)
Change in fair value of stock warrants	—	272,030	—	(3,011,574)
Total other expense, net	(893,780)	(933,516)	(2,896,950)	(6,554,531)
Net loss	$(19,899,396)	$(13,061,033)	$(61,057,928)	$(39,525,387)
Other comprehensive gain or loss:				
Unrealized gain on short-term investments	6,529	—	18,811	—
Comprehensive loss	$(19,892,867)	$(13,061,033)	$(61,039,117)	$(39,525,387)
Net loss per share, basic and diluted	$(0.85)	$(60.96)	$(2.64)	$(187.33)
Weighted average shares used to compute basic and diluted net loss per share	23,472,150	214,269	23,170,665	210,996

See accompanying notes to condensed financial statements.

TANDEM DIABETES CARE, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30, 2014	2013
Operating activities		
Net loss	$(61,057,928)	$(39,525,387)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	3,084,774	2,463,022
Provision for allowance for doubtful accounts	104,726	144,050
Provision for inventory reserve	163,246	435,419
Interest expense related to amortization of debt discount and debt issuance costs	175,808	160,565
Change in fair value of common and preferred stock warrants	—	3,011,574
Amortization of premium/discount on short-term investments	(32,713)	—
Stock-based compensation expense	11,047,973	1,609,675
Other	—	14,132
Changes in operating assets and liabilities:		
Restricted cash	—	(177,800)
Accounts receivable	(649,073)	(1,899,014)
Inventory	(1,772,338)	(4,851,688)
Prepaid and other current assets	391,774	812,580
Other long term assets	(150,000)	—
Accounts payable	615,963	(157,918)
Accrued expense	(683,082)	849,818
Employee-related liabilities	2,491,706	2,730,448
Deferred revenue	226,720	(1,712,159)
Other current liabilities	(1,822,330)	1,315,502
Deferred rent	1,289,451	(431,211)
Other long term liabilities	334,483	252,597
Payments received on note receivable from employees	—	25,000
Net cash used in operating activities	$(46,240,840)	$(34,930,795)
Investing activities		
Purchase of short-term investments	(61,855,984)	—
Proceeds from sales and maturities of short-term investments	22,710,000	—
Purchase of property and equipment	(5,259,831)	(2,530,041)
Purchase of patents	(173,200)	(2,000,000)
Net cash used in investing activities	$(44,579,015)	$(4,530,041)
Financing activities		
Issuance of notes payable, net of issuance costs	29,925,000	28,874,504
Restricted cash in connection with notes payable and corporate credit card	50,000	(2,000,000)
Principal payments on notes payable	(30,000,000)	(4,396,323)
Issuance of preferred stock for cash, net of offering costs	—	15,990,891
Proceeds from issuance of common stock	2,017,791	14,687
Deferred initial public offering costs	—	(635,630)
Net cash provided by financing activities	$1,992,791	$37,848,129
Net decrease in cash and cash equivalents	$(88,827,064)	$(1,612,707)
Cash and cash equivalents at beginning of period	$124,385,137	$17,162,730

Cash and cash equivalents at end of period	$35,558,073	$15,550,023
Supplemental disclosures of cash flow information		
Interest paid	$2,800,417	$3,666,516
Supplemental schedule of noncash investing and financing activities		
Unrealized gain on short-term investments	$18,811	$—
Property and equipment included in accounts payable	$45,910	$32,549
Deferred initial public offering costs included in accounts payable	$—	$1,127,856
Common and preferred stock warrants issued, including incremental value of modification of warrants	$—	$437,268

See accompanying notes to condensed financial statements.

TANDEM DIABETES CARE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

1. Organization and Basis of Presentation

The Company

Tandem Diabetes Care, Inc. is a medical device company focused on the design, development and commercialization of products for people with insulin-dependent diabetes. Unless the context requires otherwise, the terms the “Company” or “Tandem” refer to Tandem Diabetes Care, Inc.

The Company designed and commercialized its flagship product, the t:slim Insulin Delivery System, or t:slim, based on its proprietary technology platform and unique consumer-focused approach. The t:slim Insulin Delivery System is comprised of the t:slim Pump and pump-related supplies that include disposable cartridges and infusion sets. The U.S. Food and Drug Administration (“FDA”) cleared t:slim in November 2011 and the Company commenced commercial sales of t:slim in the United States in the third quarter of 2012.

Tandem was originally incorporated in the state of Colorado on January 27, 2006 under the name Phluid, Inc. On January 7, 2008, the Company was reincorporated in the state of Delaware for the purposes of changing its legal name from Phluid, Inc. to Tandem Diabetes Care, Inc. and changing its state of incorporation from Colorado to Delaware.

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 with 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 have been included.

Interim financial results are not necessarily indicative of results anticipated for the full year. 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, 2013, from which the balance sheet information herein was derived.

Initial Public Offering

In November 2013, the Company completed its initial public offering of 8,000,000 shares of its common stock at a public offering price of $15.00 per share. Net cash proceeds from the initial public offering were approximately $108.3 million, after deducting underwriting discounts, commissions and estimated offering related transaction costs payable by the Company. In November 2013, the underwriters also exercised their overallotment option and purchased an additional 1,200,000 shares of the Company's common stock, from which the Company received cash proceeds, net of underwriting discounts and commissions, of approximately $16.7 million. In connection with the closing of the initial public offering, all of the Company's shares of convertible preferred stock outstanding at the time of the offering were automatically converted into 13,403,747 shares of common stock. In addition, all outstanding preferred stock warrants were automatically converted into warrants to purchase an aggregate of 1,171,352 shares of common stock.

Reverse Stock Splits

In October 2013, the Board of Directors approved a 1-for-1.6756 reverse stock split of the Company's common stock. All share and per share information included in the accompanying unaudited condensed financial statements and notes to the unaudited condensed financial statements give retroactive effect to this reverse stock split of the common stock.

Voluntary Recall

On January 10, 2014, the Company announced a voluntary recall of select lots of cartridges used with the t:slim that may have been at risk of leaking. The cause of the recall was identified during the Company’s internal product testing. The recall was expanded on January 20, 2014 to include additional lots of affected cartridges used with the t:slim. The Company incurred approximately $1.7 million in direct costs associated with the recall. The Company recorded a cost of sales charge of approximately $1.3 million in the fourth quarter of 2013 and recorded a cost of sales charge for the remainder in the first quarter of 2014 for affected cartridges shipped in 2014. The Company does not currently expect any further direct financial impact of the recall beyond these costs. The total cost of the recall consisted of approximately $0.7 million associated with the return and replacement of affected cartridges in the field and approximately $1.0 million for the write-off of affected cartridges within the Company’s internal inventory.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of the financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities in the Company’s financial statements and accompanying notes as of the date of the financial statements. Actual results could differ from those estimates and assumptions.

Restricted Cash

Restricted cash as of September 30, 2014 represents a $2.0 million minimum cash balance requirement in connection with the Capital Royalty Term Loan (see Note 6 “Loan Agreements”).

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. Accounts are written off against the allowance after appropriate collection efforts have been exhausted and when it is deemed that a balance is uncollectible.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, short-term investments and accounts receivable. The Company maintains deposit accounts in federally insured financial institutions in excess of federally insured limits. The Company also maintains investments in money market funds that are not federally insured. Additionally, the Company has established guidelines regarding investment instruments and their maturities, which are designed to preserve principal and maintain liquidity.

The following table summarizes customers who accounted for 10% or more of net accounts receivable:

	September 30, 2014		December 31, 2013	
Byram Healthcare	18.5	%	N/A	
CCS Medical, Inc.	13.8	%	21.4	%
Edgepark Medical Supplies, Inc.	13.5	%	13.1	%

The following table summarizes customers who accounted for 10% or more of sales for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Edgepark Medical Supplies, Inc.	14.6%	17.2%	15.6%	17.1%
Byram Healthcare	14.3%	N/A	N/A	N/A
CCS Medical, Inc.	10.9%	15.8%	13.8%	11.6%

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 value because of the short-term nature of these items. Short-term investments are carried at fair value. Based on the borrowing rates currently available for loans with similar terms, the Company believes that the fair value of its long-term debt approximates its carrying value.

Revenue Recognition

Revenue is generated in the United States from the sale of the t:slim Pump, disposable cartridges and infusion sets to individual customers and third-party distributors that resell the product to insulin-dependent diabetes customers. Sales to distributors accounted for 72% and 71% of our total sales for the nine months ended September 30, 2014 and 2013, respectively. 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 concluding whether collectability is reasonably assured.

Prior to the first quarter of 2013, t:slim Pump sales were recorded as deferred revenue until the Company’s 30-day right of return expired because the Company did not have sufficient sales history to be able to reasonably estimate returns. At December 31, 2012, $1.9 million was recorded as deferred revenue. Beginning in the first quarter of 2013, the Company began recognizing t:slim Pump revenue when all the revenue recognition criteria above are met, as it established sufficient history in order to reasonably estimate product returns. As a result of this change, a one-time adjustment was recorded during the nine month period ended September 30, 2013, to recognize previously deferred revenue and cost of sales of $1.9 million and $1.1 million, respectively.

Revenue Recognition for Arrangements with Multiple Deliverables

The Company considers the deliverables in its product offering as separate units of accounting and recognizes deliverables as revenue upon delivery only if (i) the deliverable has standalone value and (ii) 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.

In February 2013, the FDA cleared t:connect, the Company's cloud-based data management application, which is made available upon purchase by t:slim Pump customers. This service is deemed an undelivered element at the time of the t:slim 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 estimated cost to provide such services, including consideration of a reasonable profit margin that is corroborated by comparable market data. The Company allocates fair value based on management's ESP to this element at the time of sale and recognizes the revenue over the four-year hosting period. Deferred revenue for the t:connect hosting services was $0.5 million and $0.2 million at September 30, 2014 and December 31, 2013, respectively. 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 for its t:slim Pump customers from the date of shipment, 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 t:slim Pump shipments in the same period. The return rate is then applied to the sales of the 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 at September 30, 2014 and December 31, 2013 was $0.2 million, which was included in accounts receivable on the Company's condensed balance sheets. Actual product returns have not differed materially from estimated amounts reserved.

Warranty Reserve

The Company generally provides a four-year warranty on its t:slim Pump to end user customers and may replace any pumps that do not function in accordance with the product specifications. Pumps returned to the Company may be refurbished and redeployed. Additionally, the Company offers a six-month warranty on t:slim cartridges and infusion sets. Estimated warranty costs are recorded at the time of shipment. Warranty costs are estimated based on the current product cost considering a mix of new and refurbished costs for the pump, actual experience and expected failure rates from test studies performed in conjunction with the clearance of the Company's product with the FDA to support the longevity and reliability of its t:slim Pump. The Company evaluates the reserve quarterly and makes adjustments when appropriate. At September 30, 2014 and December 31, 2013, the warranty reserve was $1.3 million and $1.1 million, respectively. Of the $1.1 million warranty reserve at December 31, 2013, $0.3 million was related to potential replacements associated with the voluntary product recall of selected lots of cartridges. The estimated reserve has been fully utilized and the Company does not expect further replacements related to this recall. As such, there was no warranty reserve at September 30, 2014 for such potential replacements. Actual warranty costs have not differed materially from estimated amounts reserved.

The following table provides a reconciliation of the change in product warranty liabilities through September 30, 2014 (in thousands):

Balance at December 31, 2013	$1,123
Provision for warranties issued during the period	2,301
Settlements made during the period	(2,114)
Balance at September 30, 2014	$1,310
Current portion recorded in other current liabilities	$360
Non-current portion recorded in other long-term liabilities	950
Total	$1,310

Stock-Based Compensation

The Company estimates the fair value of stock options and shares issued to employees 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, risk-free rate, and the fair value of the underlying common stock. For awards that vest based on service conditions, the Company recognizes expense using the straight-line method less estimated forfeitures. Prior to the Company’s initial public offering, the estimated fair value of these awards was determined at the date of grant based upon the estimated fair value of the Company’s common stock. Subsequent to the Company’s initial public offering, the fair value of the common stock is based on observable market prices. As of September 30, 2014, there were no outstanding equity awards with market or performance conditions.

The Company also records the expense for stock option grants to non-employees based on the estimated fair value of the stock option using the Black-Scholes option-pricing model. The fair value of non-employee awards is remeasured at each reporting period as the underlying awards vest unless the instruments are fully vested, immediately exercisable and nonforfeitable on the date of grant.

Warrant Liabilities

The Company issued freestanding warrants to purchase shares of common stock and convertible preferred stock in connection with the issuance of convertible notes payable in 2011 and 2012. The Company accounted for these warrants as a liability in the financial statements because either the Company did not have enough authorized shares to satisfy potential exercise of the common stock warrants and the number of shares to be issued upon their exercise was outside the control of the Company, or because the underlying instrument into which the warrants were exercisable (Series D convertible preferred stock) contained deemed liquidation provisions that were outside of the control of the Company. Upon the closing of the initial public offering, warrants to purchase shares of Series D Preferred Stock automatically converted into warrants to purchase shares of common stock. The Company reclassified the warrant liability to stockholders' equity as the warrants met the definition of an equity instrument.

Prior to the warrants being converted to an equity instrument, the warrants were recorded at fair value using either the Black-Scholes option pricing model or a binomial lattice model, depending on the characteristics of the warrants at the time of the valuation. The fair value of these warrants was remeasured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense) in the accompanying statements of operations and comprehensive loss. For the three and nine months ended September 30, 2013, income of $0.3 million and expense of $3.0 million were recorded as other income and expense from the revaluations, respectively. In connection with the completion of the initial public offering in November 2013, the Company performed the final remeasurement of the warrant liability.

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 convertible preferred stock, preferred stock warrants, common stock warrants, potential ESPP shares, restricted common stock and options outstanding under the Company's equity incentive plans. Applicable accounting guidance provides that a contract that is reported as an asset or liability for accounting purposes may require an adjustment to the numerator of the diluted earnings per share calculation for any changes in income or loss that would result if the contract had been reported as an equity instrument during the period. Securities are assumed to be converted at the beginning of the period, and the resulting common shares are included in the denominator of the diluted earnings per share calculation for the entire period presented. 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 common stock equivalent shares):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Convertible preferred stock outstanding	—	13,148,484	—	12,314,967
Warrants for convertible preferred stock	—	1,426,704	—	1,426,704
Warrants for common stock	1,006,577	271,834	1,006,577	256,898
Common stock options	2,292,897	1,716,845	2,279,347	967,857
ESPP	139,145	—	139,145	—
Restricted common stock subject to repurchase	—	58,555	—	55,633
	3,438,619	16,622,422	3,425,069	15,022,059

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board ("FASB") issued an accounting standards update, which requires management of public and private companies to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued (or available to be issued when applicable) and, if so, disclose that fact. Management will be required to make this evaluation for both annual and interim reporting periods, if applicable. Management is also required to evaluate and disclose whether its plans alleviate that doubt. The standard is effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. The Company does not believe the adoption of this standard will have a material impact on its financial position, results of operations or related financial statement disclosures.

In May 2014, the FASB and the International Accounting Standards Board ("IASB") issued a comprehensive new revenue recognition standard that will supersede existing revenue guidance under U.S. GAAP and International Financial Reporting Standards ("IFRS"). 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. These 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. The guidance is effective for annual periods beginning after December 15, 2016, including interim periods within that period. The Company is in the process of assessing the future impact of the adoption of the standard on its financial statements.

In April 2014, the Financial Accounting Standards Board ("FASB") issued an accounting standards update, which includes amendments that change the requirements for reporting discontinued operations and require additional disclosures about discontinued operations. Under the new guidance, only disposals representing a strategic shift in operations - that is, a major effect on the organization's operations and financial results - should be presented as discontinued operations. Examples include a disposal of a major geographic area, a major line of business, or a major equity method investment. Additionally, the update requires expanded disclosures about discontinued operations that will provide financial statement users with more information about the assets, liabilities, income, and expenses of discontinued operations. The guidance is effective prospectively for fiscal years beginning after December 15, 2014 and interim periods within annual periods beginning on or after December 15, 2015. The Company does not believe the adoption of this standard will have a material impact on its financial position, results of operations or related financial statement disclosures.

3. Short-Term Investments

The Company invests excess cash in investment securities, principally debt instruments of financial institutions, government sponsored enterprise securities and corporations with strong credit ratings. The following represents a summary of the estimated fair value of short-term investments at September 30, 2014 and December 31, 2013 (in thousands):

At September 30, 2014	Maturity (in years)	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Commercial paper	Less than 1	$ 40,769	$ 19	$ —	$ 40,788
Government-sponsored enterprise securities	1 to 2	3,505	—	—	3,505
Trading securities — mutual funds held for nonqualified deferred compensation plan participants		26	—	—	26
Total		$ 44,300	$ 19	$ —	$ 44,319

At December 31, 2013	Maturity (in years)	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Commercial paper	Less than 1	$ 5,095	$ —	$ —	$ 5,095
Total		$ 5,095	$ —	$ —	$ 5,095

4. Inventory

Inventories, stated at the lower of cost or market, consisted of the following (in thousands):

	September 30, 2014	December 31, 2013
Raw materials	$ 6,098	$ 6,363
Work in process	3,832	2,169
Finished goods	2,191	3,535
	12,121	12,067
Less reserve	(229)	(1,737)
Total	$ 11,892	$ 10,330

The inventory reserve at December 31, 2013 included $0.9 million associated with the Company's voluntary product recall. There was no reserve associated with the product recall at September 30, 2014.

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 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 quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2014 and December 31, 2013, and indicates the fair value hierarchy of the valuation techniques utilized by the Company to determine such fair value (in thousands):

	September 30, 2014	Fair Value Measurements at September 30, 2014		
		Level 1	Level 2	Level 3
Assets				
Cash equivalents (1)	$ 31,801	$31,801	$—	$ —
Restricted cash	2,000	2,000	—	—
Commercial paper	40,788	—	40,788	—
Mutual funds held for nonqualified deferred compensation plan participants (2)	26	26	—	—
Government-sponsored enterprise securities	3,505	3,505	—	—
Total assets	$ 78,120	$37,332	$40,788	$ —
Liabilities				
Deferred compensation (2)	$ 26	$26	$—	$ —
Total liabilities	$ 26	$26	$—	$ —

(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.

	December 31, 2013	Fair Value Measurements at December 31, 2013		
		Level 1	Level 2	Level 3
Assets				
Money market funds	$115,112	$115,112	$—	$ —
Restricted cash	2,050	2,050	—	—
Commercial paper	5,095	—	5,095	—
Total assets	$122,257	$117,162	$5,095	$ —

The Company's Level 2 financial instruments are valued using market prices on less active markets and model-derived valuations 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 nine months ended September 30, 2014.

6. Loan Agreements

Silicon Valley Bank Loan

In March 2012, the Company entered into a Loan and Security Agreement with Silicon Valley Bank (“SVB”), drawing a bridge loan in the amount of $5.0 million (the “SVB Bridge Loan”). Subsequent to the closing of the Series D financing, the SVB Bridge Loan was converted into a 24-month term loan (the “SVB Term Loan”) in September 2012. The term loan accrued interest at an annual rate of 4%, with principal and accrued interest payments due monthly throughout the 24-month term. The SVB Term Loan also required a final payment of $0.3 million and a fee of $0.2 million if the loan was prepaid in its entirety prior to the end of the term of the loan.

In connection with the SVB Bridge Loan and SVB Term Loan, the Company issued an aggregate of 102,270 warrants to purchase shares of Series D convertible preferred stock at an exercise price of $4.40 per share. In November 2013, in connection with the closing of the initial public offering, all SVB Series D Preferred Stock warrants automatically converted into warrants to purchase 61,033 shares of our Common Stock at a weighted average exercise price of $7.37 per share.

In conjunction with the Capital Royalty Term Loan closing in January 2013, all principal, interest due and prepayment fee amounts due under the SVB Term Loan were paid by the Company.

Silicon Valley Bank Revolving Line of Credit

In January 2013, the Company entered into an amended loan agreement with Silicon Valley Bank, making available a revolving line of credit in an amount up to the lesser of $1.5 million or 75% of eligible accounts receivable, and expiring in January 2015. Interest-only payments at a rate of 6% per annum are payable monthly through the maturity date. Loans drawn under the agreement are secured by eligible accounts receivable and proceeds therefrom. Additionally, the terms of the revolving line of credit contain various affirmative and negative covenants. There were no amounts outstanding under this loan as of September 30, 2014 or December 31, 2013.

Capital Royalty Term Loan

In December 2012, the Company executed a Term Loan Agreement (the “Original Term Loan Agreement”) with Capital Royalty Partners II L.P. (“Capital Royalty Partners”) and Capital Royalty Partners II—Parallel Fund “A” L.P. (“CRPPF,” together with Capital Royalty Partners, the “Lenders”), providing the Company access to up to $45.0 million under the arrangement, of which $30.0 million was available in January 2013. An additional amount up to $15.0 million became available upon achievement of a 2013 revenue-based milestone. In January 2013, $30.0 million was drawn under the Original Term Loan Agreement. The loan under the Original Term Loan Agreement accrued interest at an annual rate of 14%. Interest-only payments were due quarterly at March 31, June 30, September 30 and December 31 of each year through December 31, 2015. Thereafter, in addition to interest accrued during the period, quarterly payments were required to include an amount equal to the outstanding principal at December 31, 2015 divided by the remaining number of quarters prior to the maturity of the loan which is December 31, 2017. The Original Term Loan Agreement stipulated prepayment fees of 5% of the outstanding balance of the loan if the loan was repaid prior to April 1, 2014. The prepayment fee was reduced 1% per year for each subsequent year until maturity.

In connection with the Original Term Loan Agreement, in January 2013, the Company issued warrants to purchase 271,834 shares of the Company's Common Stock at an exercise price of $0.02 per share. The warrants were immediately exercisable and expire in January 2023. Because the exercise price of these warrants is nominal, the Company used the fair value of the common stock of $1.61 at December 31, 2012 to value these warrants. The Company also paid a $0.4 million financing fee to the Lenders. The warrants' fair value of approximately $0.4 million and the financing fee of $0.4 million were recorded as a debt discount. Additionally, the Company paid $0.7 million to a third party for sourcing the Capital Royalty Term Loan, which was recorded as debt issuance cost, within other long term assets on the condensed balance sheets. The fees and the value of the warrants are amortized to interest expense over the remaining term using the effective interest method.

In April 2014, the Company entered into an Amended and Restated Term Loan Agreement (the “Amended and Restated Term Loan Agreement”) with the Lenders and other parties affiliated with Capital Royalty Partners. The Amended and Restated Term Loan Agreement primarily amends the terms of the Original Term Loan Agreement to reduce the borrowing limit to $30.0 million, to reduce the applicable interest rate from 14.0% to 11.5%, and to extend the interest only payment period from December 31, 2015 to March 31, 2018. Interest is payable, at the Company’s option, (i) in cash at a rate of 11.5% per annum or (ii) 9.5% of the 11.5% per annum in cash and 2.0% of the 11.5% per annum is added to the principal of the loan and is 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. Thereafter, in addition to interest accrued during the period, the quarterly payments shall include an amount equal to the outstanding principal at March 31, 2018 divided by the remaining number of quarters prior to the end of the term of the loan which is March 31, 2020. The Amended and Restated Term Loan Agreement provides for prepayment fees of 3% of the outstanding balance of the loan if the loan is repaid prior to March 31, 2015. The prepayment fee is reduced by 1% per year for each subsequent year until maturity.

Certain affirmative and negative covenants were also amended. The principal financial covenants require that the Company attain minimum annual revenues of $30.0 million in 2014, $50.0 million in 2015, $65.0 million in 2016, $80.0 million in 2017 and $95.0 million thereafter. As of September 30, 2014, the Company had already met the minimum annual revenue threshold for 2014.

Aggregate borrowings outstanding under the Amended and Restated Term Loan Agreement are $30.0 million. Borrowings under the Amended and Restated Term Loan Agreement were used to refinance amounts outstanding under the Original Term Loan Agreement. The present value of the future cash flows under the modified terms described above did not exceed the present value of the future cash flows under the original terms by more than 10%. The Company treated this amendment as a modification and the facility fee of approximately $0.1 million recorded as a discount to the Amended and Restated Term Loan. The facility fee and the remaining balance of debt issuance cost and debt discount of the Original Term Loan are amortized over the remaining term of the Amended and Restated Term Loan using the effective interest method.

Concurrently, the Company also entered into a new Term Loan Agreement (the “New Tranche Term Loan Agreement”) with the Lenders and other parties affiliated with Capital Royalty Partners, under which the Company may borrow up to an additional $30.0 million on or before March 31, 2015 at the same interest rate and on the same key terms as the Amended and Restated Term Loan Agreement.

7. Stockholders’ Equity

Shares Reserved for Future Issuance

The following shares of common stock are reserved for future issuance at September 30, 2014:

Common stock warrants outstanding	1,006,577
Stock options issued and outstanding	4,899,528
Authorized for future option grants	2,149,102
Employee stock purchase plan	659,863
	8,715,070

The Company issued 106,801 shares of common stock upon the exercise of stock options and warrants during the nine months ended September 30, 2014, and issued 95,007 shares of common stock upon the exercise of stock options and warrants during the year ended December 31, 2013.

In October 2013, the Company adopted the 2013 Employee Stock Purchase Plan (“2013 ESPP”). During the nine months ended September 30, 2014, there were 125,393 shares of common stock purchased under the 2013 ESPP.

Stock-Based Compensation

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

	Stock Option Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Risk-free interest rate	1.9 %	1.8 %	1.9 %	1.1 %
Expected dividend yield	0.0 %	0.0 %	0.0 %	0.0 %
Expected volatility	78.1%	79.4%	78.7%	76.6%
Expected term (in years)	6.1	5.7	6.1	5.6

	ESPP Nine Months Ended September 30,	
	2014	2013
Risk-free interest rate	0.2 %	—
Expected dividend yield	0.0 %	—
Expected volatility	62.9%	—
Expected term (in years)	1.3	—

There were no ESPP valuations performed during the three months ended September 30, 2014.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Cost of sales	$313	$(9)	$940	$58
Selling, general & administrative	2,979	861	8,798	1,370
Research and development	454	114	1,310	183
Total	$3,746	$966	$11,048	$1,611

The total stock-based compensation capitalized as part of the cost of inventory was $0.2 million and $0.3 million at September 30, 2014 and December 31, 2013, respectively.

8. Collaborations

DexCom Development and Commercialization Agreement

In February 2012, the Company entered into a Development and Commercialization Agreement with DexCom, Inc. (the “DexCom Agreement”) for the purpose of collaborating on the development and commercialization of an integrated system which incorporates the t:slim Insulin Delivery System with DexCom’s proprietary continuous glucose monitoring system. Under the DexCom Agreement, the Company paid DexCom $1.0 million in 2012 at the commencement of the collaboration and a $1.0 million milestone payment in July 2014, which related to the Company’s submission of a pre-market approval (“PMA”) application for the t:slim G4, which the Company has previously referenced as t:sensor, to the FDA. The payments were recorded as research and development costs. The Company will make one additional $1.0 million payment upon the achievement of certain milestones. Additionally, the Company will reimburse DexCom up to $1.0 million of its development costs and is solely responsible for its own development costs. As of September 30, 2014, the Company has reimbursed DexCom $0.2 million of its development costs. The Company recognized research and development costs of $32,000 and $78,000 for the nine months ended September 30, 2014 and 2013, respectively. The research and development costs recognized for the three months ended September 30, 2014, and 2013 were not significant.

Upon commercialization of the integrated system, and as compensation for the non-exclusive license rights, the Company will also pay DexCom a royalty of $100 for each integrated system sold.

Juvenile Diabetes Research Foundation Collaboration

In January 2013, the Company entered into a research, development and commercialization agreement (“JDRF Agreement”) with the Juvenile Diabetes Research Foundation (“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 will 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. The research and development milestones are anticipated to be reached by September 2016. Payments the Company receives to fund the collaboration efforts under the terms of the JDRF Agreement will be recorded as restricted cash and current and long-term liabilities. The liabilities are 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 is utilized to fund such development activities.

As of September 30, 2014, milestone payment achievements totaled $0.7 million, and research and development costs were offset cumulatively by $0.3 million. The research and development costs were offset by $37,000 and $146,000 for the three and nine-months ended September 30, 2014, respectively. For the three and nine months ended September 30, 2013, research and development costs were offset by $63,000 and $145,000, respectively. The Company did not have any restricted cash balances related to the JDRF Agreement at September 30, 2014 or December 31, 2013.

9. Commitments and Contingencies

From time to time, the Company may be subject to legal or regulatory proceedings or other matters arising in the ordinary course of business, including proceedings with respect to intellectual property, employment, product liability, and contractual matters. The Company assesses, on a regular basis, the probability of a negative outcome and the range of possible loss based on the developments with respect to these matters. A liability is only recorded in the financial statements if it is believed to be probable that a loss has been incurred and that 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 proceedings, the Company is currently unable to predict their ultimate outcome, and, with respect to any pending litigation or claim where no liability has been accrued, to make a meaningful estimate of the reasonably possible loss or range of loss that could result from an unfavorable outcome. At September 30, 2014 and December 31, 2013, there were no pending legal or regulatory proceedings for which a negative outcome was considered probable and for which the loss could be reasonably estimated. As a result, no amounts have been accrued with respect to any such proceedings at either date.

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Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2013 included with our Annual Report on Form 10-K for the year ended December 31, 2013 filed with the Securities and Exchange Commission, or SEC. Operating results are not necessarily indicative of results that may occur in future periods.

Certain statements contained in this Quarterly Report on Form 10-Q, including statements regarding the development, growth and expansion of our business, our intent, belief or current expectations, primarily with respect to our projected financial and operating performance, and the products we expect to offer in the future, and other statements that are not statements of historical fact, are “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act, and are subject to the “safe harbor” created by these sections. Future filings with the SEC, future press releases and future oral or written statements made by us or with our approval, which are not statements of historical fact, may also contain forward-looking statements. Because such statements include risks and uncertainties, many of which are beyond our control, actual results may differ materially from those expressed or implied by such forward-looking statements. Some of the factors that could cause actual results to differ materially from those expressed or implied by such forward-looking statements can be found under the caption “Risk Factors,” and elsewhere in this Quarterly Report on Form 10-Q as well as in our other filings with the SEC. Readers are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made.

Overview

We are a medical device company with an innovative approach to the design, development and commercialization of products for people with insulin-dependent diabetes. We designed and commercialized our flagship product, the t:slim Insulin Delivery System, or t:slim, based on our proprietary technology platform and unique consumer-focused approach. 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 embedded software architecture, a vivid color touchscreen and a micro-USB connection that supports both a rechargeable battery and t:connect, our data management application. Our innovative approach to product design and development is also consumer-focused and based on our extensive market research as we believe the user is the primary decision maker when purchasing an insulin pump. We also apply the science of human factors to our design and development process, which seeks to optimize our devices to the intended users, allowing users to successfully operate our devices in their intended environment. Leveraging our technology platform and consumer-focused approach, we develop products to address unmet needs of people in all segments of the large and growing insulin-dependent diabetes market.

The FDA cleared t:slim in November 2011. We commenced commercial sales of t:slim in the United States in the third quarter of 2012. We consider the number of units shipped per quarter to be an important metric for managing our business. Since the launch of t:slim, we have shipped approximately 14,400 pumps as of September 30, 2014, broken down by quarter as follows:

	Units Shipped for Each of the Three Month Periods		
	2012	2013	2014
March 31	N/A	852	1,723
June 30	9	1,363	2,235
September 30	204	1,851	2,935
December 31	844	2,406	N/A
Total	1,057	6,472	6,893

For the three months ended September 30, 2014 and 2013, our sales were $13.5 million and $7.8 million, respectively. For the three months ended September 30, 2014 and 2013, our net loss was $19.9 million and $13.1 million, respectively.

For the nine months ended September 30, 2014 and 2013, our sales were $31.8 million and $18.8 million, respectively. For the nine months ended September 30, 2014 and 2013, our net loss was $61.1 million and $39.5 million, respectively. Our accumulated deficit as of September 30, 2014 was $230.2 million.

We have derived nearly all of our revenue from the sale of t:slim in the United States and expect to continue to do so until we are able to commercialize our other products that are currently under development, including the t:slim G4™ Insulin Pump System, for which we submitted a PMA application to the FDA during the three months ended September 30, 2014. We also recently submitted a 510(k) application to the FDA for the t:flex Insulin Pump, which will include the same product platform, technology and user interface as t:slim, but will offer a 480 unit insulin cartridge. A substantial portion of the purchase price of an insulin pump is typically paid for by third-party payors, including private insurance companies, preferred provider organizations and other managed care providers. Future sales of our current and future products will be limited unless our customers can rely on third-party payors to pay for all or part of the associated purchase cost. Access to adequate coverage and reimbursement for our current and future products by third-party payors is essential to the acceptance of our products by customers. In circumstances that we do not have contracts established with third-party payors, to the extent possible we utilize our network of national and regional distributors to service our customers.

We believe we can achieve profitability because our proprietary technology platform will allow us to maximize efficiencies in the development, production and sales of our products. By leveraging our core technology, we believe we can develop and bring to market products rapidly and greatly reduce our design and development costs. We expect to continue to increase production volume, and to reduce the per unit production cost for the t:slim Pump and its disposable cartridge over time. Further, 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. By expanding our product offerings to address people in all segments of the large and growing insulin-dependent diabetes market, we believe we can increase the productivity of our sales force, thereby improving our operating margin.

From inception through September 30, 2014, 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 financings and debt financings in order to fund our operations to a level of revenues adequate to support our cost structure.

We have experienced considerable revenue 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 and our growth or operating results may not be consistent with predictions made by securities analysts. 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 on Form 10-Q.

Voluntary Recall

On January 10, 2014, we announced a voluntary recall of select lots of cartridges used with the t:slim that may have been at risk of leaking. The cause of the recall was identified during our internal product testing. The recall was expanded on January 20, 2014 to include additional lots of affected cartridges used with the t:slim. We incurred approximately $1.7 million in direct costs associated with the recall. We recorded a cost of sales charge of approximately $1.3 million in the fourth quarter of 2013 and recorded the cost of sales charge for the remainder in the first quarter of 2014 for affected cartridges shipped in the first quarter of 2014. We do not currently expect any further direct financial impact of the recall beyond these costs. The total cost of the recall consisted of approximately $0.7 million associated with the return and replacement of affected cartridges in the field and approximately $1.0 million for the write-off of affected cartridges within our internal inventory.

Components of Results of Operations

Sales

We commenced commercial sales of t:slim in the United States in the third quarter of 2012. The t:slim Insulin Delivery System is comprised of the t:slim Pump and pump-related supplies that include 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 co-insurance requirements.

We anticipate our sales will increase as we expand our sales and marketing infrastructure, increase awareness of our products and broaden third party reimbursement for our products. We also expect that our sales will fluctuate on a quarterly basis in the future due to a variety of factors, including seasonality and the impact of the buying patterns of our distributors and other customers. We believe that our sales are subject to seasonal fluctuation due to the impact of annual deductible and coinsurance requirements associated with most medical insurance plans utilized by our individual customers and the individual customers of our distributors. Our sales may also be influenced by the summer vacation period. Accordingly, we have experienced and expect to continue to experience sequential growth of sales in each quarter from the first quarter to the fourth quarter, and we also expect sequential sales from the fourth quarter to the first quarter to be relatively flat or down.

Cost of Sales

We manufacture the t:slim Pump and its disposable cartridge at our manufacturing facility in San Diego, California. Infusion sets and t:slim accessories are manufactured by third-party suppliers. Cost of sales includes raw materials, labor costs, manufacturing overhead expenses, product training costs and reserves for expected warranty costs, scrap and inventory obsolescence. Due to our relatively low production volumes compared to our potential capacity to produce our products, manufacturing overhead expenses are a significant portion of our per unit costs. These expenses include quality assurance, manufacturing engineering, material procurement, inventory control, facilities, equipment, information technology and operations supervision and management.

We expect our overall gross margin, which is calculated as sales less cost of sales for a given period divided by sales, to fluctuate in future periods as a result of the changing percentage of products sold to distributors versus directly to individual customers, varying levels of reimbursement among third-party payors, changing mix of products sold with different gross margins, and changes in our manufacturing processes, costs or manufacturing output. Manufacturing inefficiencies will also impact our gross margins, which we may experience as we attempt to manufacture our products on a larger scale, change our manufacturing capacity or output, and expand our manufacturing facilities. Any new products that we sell in the future may also change our gross margins.

Selling, General and Administrative

We expect our selling, general and administrative, or SG&A, expenses to increase as our business expands. Our SG&A expenses primarily consist of salary, fringe benefits and stock-based compensation for our executive, financial, marketing, sales, business development, regulatory affairs and administrative functions. Other significant expenses include those incurred for product demonstration samples, trade shows, outside legal counsel fees, independent auditor fees, outside consultant fees, insurance premiums, facilities costs and information technology costs.

Research and Development

We expect our research and development, or R&D, expenses to increase as we initiate and advance our development projects. Our 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, stock-based compensation and temporary employee expenses. We also incur significant expenses for supplies, development prototypes, outside design and testing services and milestone payments under our development and commercialization agreements with DexCom and other collaborators.

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 term loan agreements. At September 30, 2014, there was $30.0 million of outstanding principal under our Amended and Restated Term Loan Agreement with the Lenders, which accrues interest at a rate of 11.5% per annum. In previous years, other income and expense also included interest expense and amortization of debt discount associated with convertible notes payable and the change in the fair value of outstanding common and preferred stock warrants for which the final revaluation was performed in connection with our initial public offering in the fourth quarter of 2013.

Results of Operations

(in thousands, except percentages)	Three Months Ended September 30, 2014	2013	Nine Months Ended September 30, 2014	2013
Sales	$13,514	$7,776	$31,834	$18,762
Cost of sales	9,117	5,243	23,121	13,783
Gross profit	4,397	2,533	8,713	4,979
Gross margin	33 %	33 %	27 %	27 %
Operating expenses:				
Selling, general and administrative	18,895	12,009	55,004	30,217
Research and development	4,508	2,652	11,870	7,733
Total operating expenses	23,403	14,661	66,874	37,950
Operating loss	(19,006)	(12,128)	(58,161)	(32,971)
Other income (expense), net:				
Interest and other income	30	—	79	1
Interest and other expense	(923)	(1,206)	(2,976)	(3,543)
Change in fair value of stock warrants	—	273	—	(3,012)
Total other expense, net	(893)	(933)	(2,897)	(6,554)
Net loss	$(19,899)	$(13,061)	$(61,058)	$(39,525)

Comparison of the Three Months Ended September 30, 2014 and 2013

Sales. We began selling our products in the third quarter of 2012. Sales for the three months ended September 30, 2014 were $13.5 million, representing an increase of 74% compared to $7.8 million for the same period in 2013. For the three months ended September 30, 2014 and 2013, sales from the t:slim Pump accounted for 86% and 89% of sales, respectively, while 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 t:slim Pump sales during the three months ended September 30, 2014 compared to the same period in 2013 was primarily attributable to the increase in the size of our sales force. The commercialization of the t:slim Pump and pump-related supplies and accessories initially involved a sales force of limited size. At September 30, 2013, we operated with 36 sales territories. During 2014, we further expanded the sales territories from 36 at the end of 2013 to 60 at the end of the third quarter of 2014. During the expansion of the sales territories in 2014, we believe our sales force experienced some initial disruption in their individual productivity as territories were realigned and responsibilities adjusted.

Sales to distributors accounted for 76% and 70% of our total sales for the three months ended September 30, 2014 and 2013, respectively. The mix of sales to distributors versus direct customers is driven by whether or not we have a contracted arrangement with the underlying third-party insurance payor. The increase in the percentage of our sales to distributors is primarily attributable to new exclusive arrangements between certain insurance payors and certain of our distributors that became effective during the third quarter of 2014. As a result of these new arrangements, a portion of our business has transitioned from a direct sale opportunity to a distributor sale. We did not have a direct billing contract with one of these payors. The new arrangement has afforded its members easier access to our products as an in-network benefit and it also provided access to our products for a large portion of members who were previously unable to obtain coverage for our products.

Cost of Sales and Gross Profit. Our cost of sales for the three months ended September 30, 2014 was $9.1 million, representing an increase of 74% compared to $5.2 million for the same period in 2013. Gross profit for the three months ended September 30, 2014 was $4.4 million and gross margin was 33%, compared to gross profit of $2.5 million and gross margin of 33% for the same period in 2013.

Our gross margin for the three months ended September 30, 2014 was comparable to gross margin in the same period of 2013. Our margins were positively affected by increased sales volumes, offset by an increase in manufacturing overhead costs of our products. We continue to increase our manufacturing operations and costs as we address increasing production volume requirements. Our manufacturing overhead costs have and will continue to be a significant component of the cost of our products, and as a result have, and may continue to impact, our gross margins as we attempt to manufacture our products on a larger scale, change our manufacturing processes, capacity or output, implement additional automated manufacturing equipment and expand our manufacturing facilities.

Also impacting the gross margin in the third quarter of 2014 as compared to the third quarter of 2013 were the varying levels of reimbursement among a changing mix of third-party payors, as well as an increase in sales of pump-related supplies. Our gross margin on the sales of the t:slim Pump was higher than pump-related supplies for the quarters ended September 30, 2014 and 2013, and is expected to remain higher in the future. These and other factors, such as the percentage of products sold to distributors versus directly to individual customers, and the gross margin associated with any new products that we sell in the future, will continue to impact our future gross margins.

Selling, General and Administrative Expenses. SG&A expenses increased 57% to $18.9 million for the three months ended September 30, 2014 from $12.0 million for the same period of 2013. The increase in SG&A expenses for the three months ended September 30, 2014 was primarily associated with the continued expansion of our commercial operations. At September 30, 2014, our headcount for sales, general and administrative functions increased by 46% compared to September 30, 2013. This includes an expansion to 60 sales territories by the end of the third quarter of 2014 from 36 at the end of the third quarter of 2013, as well as the growth of the administrative infrastructure to support the growing operations. A territory is maintained by sales representatives, field clinical specialists, 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. Such employee-related expenses increased $6.0 million during the three months ended September 30, 2014 compared to the same periods in 2013, including an increase of $2.1 million in stock-based compensation associated with equity awards. SG&A expenses also increased $0.9 million associated with marketing and promotional activities, tradeshows, travel expenses and facility expansion.

Research and Development Expenses. R&D expenses increased 70% to $4.5 million for the three months ended September 30, 2014 from $2.7 million for the same periods of 2013. The increase in R&D expenses consisted primarily of a milestone payment of $1.0 million made to DexCom under the DexCom Agreement related to our submission of a pre-market approval (“PMA”) application for the t:slim G4, which we have previously referenced as t:sensor, to the FDA in July 2014. R&D expense also increased $0.7 million in employee-related expenses. At September 30, 2014, our headcount for research and development functions increased by 13% compared to September 30, 2013.

Other Income and Expense. Other expense for the three months ended September 30, 2014 and 2013 was $0.9 million. Other expense for the third quarter of 2014 was primarily comprised of $0.9 million interest expense associated with the Amended and Restated Term Loan Agreement, which was executed in April 2014.

In comparison, other expense for the third quarter of 2013 was primarily comprised of a $0.3 million decrease in the fair value of the common and preferred stock warrants and $1.2 million interest expense associated with the Original Term Loan Agreement. The decrease in interest expense during the third quarter of 2014 compared to the same period in 2013 is due to the decrease in the interest rate on our outstanding debt from 14% to 11.5% in conjunction with the Amended and Restated Term Loan Agreement.

Comparison of the Nine Months Ended September 30, 2014 and 2013

Sales. Sales for the nine months ended September 30, 2014 were $31.8 million, representing an increase of 70% compared to $18.8 million for the same period in 2013. Sales for the nine months ended September 30, 2013 included a one-time adjustment for recognition of $1.9 million of t:slim Pump sales that were previously deferred in the fourth quarter of 2012 due to our lack of history for estimating product returns at that time. For the nine months ended September 30, 2014 and 2013, sales from the t:slim Pump accounted for 86% and 91% of sales, respectively, while pump-related supplies primarily accounted for the remainder of our sales in each of those periods. Sales of accessories were not material in either of the reported periods. Sales to distributors accounted for 72% and 71% of our total sales for the nine months ended September 30, 2014 and 2013, respectively. The increase in t:slim Pump sales during the nine months ended September 30, 2014 compared to the same period in 2013 was primarily attributable to the increase in the size of our sales force during the relevant periods.

Cost of Sales and Gross Profit. Our cost of sales for the nine months ended September 30, 2014 was $23.1 million, representing an increase of 68% compared to $13.8 million for the same period in 2013. Gross profit for the nine months ended September 30, 2014 was $8.7 million, and gross margin was 27%, compared to gross profit of $5.0 million, and gross margin of 27% for the same period in 2013.

Included in cost of sales for the nine months ended September 30, 2014 were costs of $0.3 million associated with our voluntary product recall of selected lots of cartridges initiated in January 2014. The voluntary recall resulted in a one percentage point reduction in the gross margin for the nine months ended September 30, 2014. Included in cost of sales for the nine months ended September 30, 2013 were costs of $1.1 million that were previously deferred at the end of the fourth quarter of 2012 due to our lack of history for estimating product returns at that time. These costs, along with the previously deferred sales of $1.9 million recognized in the first quarter of 2013, resulted in a two percentage point increase in gross margin of the first nine months of 2013.

Selling, General and Administrative Expenses. SG&A expenses increased 82% to $55.0 million for the nine months ended September 30, 2014 from $30.2 million for the same period of 2013. The increase in SG&A expenses for the nine months ended September 30, 2014 was primarily associated with the continued expansion of our commercial operations. At September 30, 2014, our headcount for sales, general and administrative functions increased by 46% compared to September 30, 2013. Employee-related expenses for our sales, general and administrative functions comprise the majority of the SG&A expenses. Such employee-related expenses increased $19.9 million during the nine months ended September 30, 2014 compared to the same period in 2013, including an increase of $7.4 million in stock-based compensation associated with equity awards. SG&A expenses also increased $4.9 million during the nine months ended September 30, 2014 compared to the same period in 2013, associated with marketing and promotional activities, tradeshows, travel expenses and facility expansion.

Research and Development Expenses. R&D expenses increased 53% to $11.9 million for the nine months ended September 30, 2014 from $7.7 million for the same period of 2013. The increase in R&D expenses consisted primarily of an increase of $2.3 million in employee-related expenses. At September 30, 2014, our headcount for research and development functions increased by 13% compared to September 30, 2013. The increase in R&D expenses also consisted a milestone payment of $1.0 million we made to DexCom under the DexCom Agreement related to our submission of a PMA for the t:Slim G4, which we have previously referenced as t:sensor, to the FDA in July 2014.

Other Income and Expense. Other expense for the nine months ended September 30, 2014 was $2.9 million compared to $6.6 million for the same period in 2013. Other expense for the first nine months of 2014 was primarily comprised of $3.0 million interest expense associated with the Original Term Loan Agreement executed in December 2012 and the Amended and Restated Term Loan Agreement executed in April 2014.

In comparison, other expense for the first nine months of 2013 was primarily comprised of a $3.0 million increase in the fair value of the common and preferred stock warrants and $3.5 million interest expense associated with the Original Term Loan Agreement. The decrease in interest expense during the first nine months of 2014 compared to the same period in 2013 is due to the decrease in the interest rate on our outstanding debt from 14% to 11.5% in conjunction with the Amended and Restated Term Loan Agreement, which was executed in April 2014.

Liquidity and Capital Resources

At September 30, 2014, we had $81.9 million in cash, cash equivalents, restricted cash and short-term investments. We believe that our cash on hand, cash available under our term loan agreement and proceeds from equity activities will be sufficient to satisfy our liquidity requirements for at least the next 18 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 and available cash will impact our decision to continue to utilize debt arrangements as a source of cash.

Historically, our sources of cash have included private placements and a public offering 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 purchase of inventory, expansion of our sales and marketing infrastructure, increase in our R&D activities and other working capital needs, as well as cash used for investing activities, such as the acquisition of intellectual property, expenditures related to equipment and improvements used to increase our manufacturing capacity and improve our manufacturing efficiency and overall facility expansion.

The following table shows a summary of our cash flows for the nine months ended September 30, 2014 and 2013:

	Nine Months Ended September 30,	
(in thousands)	2014	2013
Net cash provided by (used in):		
Operating activities	$(46,241)	$(34,931)
Investing activities	(44,579)	(4,530)
Financing activities	1,993	37,848
Total	$(88,827)	$(1,613)

Operating activities. Net cash used in operating activities was $46.2 million for the nine months ended September 30, 2014, compared to $34.9 million for the same period in 2013. The increase in net cash used in operating activities was primarily associated with increased costs related to the continued expansion of commercial operations. Our employee headcount, employee-related expenses and working capital needs, including accounts receivable and inventory, increased significantly as a result of our expansion of commercial operations. Additionally, we made a milestone payment of $1.0 million to DexCom and final payments totaling $2.0 million for licensing fees based on previously disclosed contractual obligations.

Investing activities. Net cash used in investing activities was $44.6 million for the nine months ended September 30, 2014, which was primarily related to the net purchase of $61.9 million in short-term investments and $5.3 million in purchases of property and equipment, offset by proceeds from sales and maturities of short-term investments of $22.7 million. Net cash used in investing activities was $4.5 million for the nine months ended September 30, 2013, which was primarily related to the purchase of $2.5 million in capital equipment, and $2.0 million of patent rights.

Financing activities. Net cash provided by financing activities was $2.0 million for the nine months ended September 30, 2014, which was primarily related to net proceeds from the exercise of outstanding stock options and warrants, as well as an ESPP purchase. Net cash provided in financing activities was $37.8 million in the first nine months of 2013, which was primarily related to net proceeds from issuance of notes payable of $28.9 million, and proceeds from issuance of preferred stock of $16.0 million, offset by principal payments on notes payable of $4.4 million.

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:

fluctuations in gross margins and operating margins;

our ability to generate sales; and

fluctuations in working capital.

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

support of our commercialization efforts related to our current and future products;

improvements in our manufacturing capacity and efficiency;

- growth of our sales, marketing and clinical infrastructure;
- new research and product development efforts;
- payment of quarterly interest due under our term debt agreement;
- the acquisition of equipment and other fixed assets;
- facilities expansion needs; and
- potential up-front fees, milestone payments or reimbursement of costs under R&D collaborations and licensing 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. Additional capital, if needed, may not be available on satisfactory terms, if at all. Furthermore, any additional equity financing may be dilutive to stockholders, and debt financing, if available, may include restrictive covenants.

Indebtedness

Capital Royalty Partners Term Loans

In December 2012, we executed a Term Loan agreement (the "Original Term Loan Agreement") with Capital Royalty Partners II L.P. ("Capital Royalty Partners") and Capital Royalty Partners II—Parallel Fund "A" L.P. ("CRPPF", together with Capital Royalty Partners, the "Lenders"), providing us access to $45.0 million under the arrangement, of which $30.0 million was available in January 2013, and an additional amount up to $15.0 million became available upon our achievement of a 2013 revenue-based milestone. In January 2013, $30.0 million was drawn under the agreement, a portion of which was used to repay all amounts outstanding under our $5.0 million loan from Silicon Valley Bank.

In April, 2014, we entered into the Amended and Restated Term Loan Agreement with the Lenders and Capital Royalty Partners II (Cayman) L.P. ("CRPC") under which we may borrow up to $30.0 million. The Amended and Restated Term Loan Agreement amends and restates the Original Term Loan Agreement.

Aggregate borrowings outstanding under the Amended and Restated Term Loan Agreement were $30 million at September 30, 2014. Borrowings under the Amended and Restated Term Loan Agreement were used to refinance amounts outstanding under the Original Term Loan Agreement.

The Amended and Restated Term Loan Agreement primarily amends the terms of the Original Term Loan Agreement to reduce the borrowing limit to $30.0 million, to reduce the applicable interest rate from 14.0% to 11.5%, and to extend the interest only payment period from December 31, 2015 to March 31, 2018. Interest is payable, at our option, (i) in cash at a rate of 11.5% per annum or (ii) 9.5% of the 11.5% per annum in cash and 2.0% of the 11.5% per annum is added to the principal of the loan and is 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. Thereafter, in addition to interest accrued during the period, the quarterly payments shall include an amount equal to the outstanding principal at March 31, 2018 divided by the remaining number of quarters prior to the end of the term of the loan. The Amended and Restated Term Loan Agreement provides for prepayment fees of 3% of the outstanding balance of the loan if the loan is repaid prior to March 31, 2015. The prepayment fee is reduced by 1% per year for each subsequent year until maturity.

Certain affirmative and negative covenants were also amended to provide us with additional flexibility. The principal financial covenants require that we attain minimum annual revenues of $30.0 million in 2014, $50.0 million in 2015, $65.0 million in 2016, $80.0 million in 2017 and $95.0 million thereafter. As of September 30, 2014, we had already met the minimum annual revenue threshold for 2014.

On the same date, we entered into the New Tranche Term Loan Agreement with the Lenders, CRPC and Parallel Investment Opportunities Partners II L.P. under which we may borrow up to an additional $30.0 million on or before March 31, 2015, at the same interest rate and on the same key terms as the Amended and Restated Term Loan Agreement.

Silicon Valley Bank Revolving Line of Credit

In January 2013, we entered into an amended loan agreement with Silicon Valley Bank, making available a revolving line of credit in the amount up to the lesser of $1.5 million or 75% of eligible accounts receivable, and expiring in January 2015. Interest-only payments at a rate of 6% per annum are payable monthly through the maturity date 24 months from the initial borrowing. Loans drawn under the agreement are secured by our eligible accounts receivable and proceeds therefrom. Additionally, the terms of the revolving line of credit contain various affirmative and negative covenants. There were no amounts outstanding under this line of credit as of September 30, 2014 and December 31, 2013. In the event of our breach of the agreement, we may not be allowed to draw amounts under the agreement, and, to the extent we have any amounts outstanding at the time of any breach, we may be required to repay such amounts earlier than anticipated.

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. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate these estimates, including those related to revenue recognition, warranty reserve, inventory reserve, capitalized intellectual property, stock-based compensation and warrant liabilities. These estimates are based on historical experience and various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for judgments about the carrying values of assets and liabilities and the recognition of revenues and expenses. Actual results may differ from these estimates under different assumptions or conditions. 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, 2013.

Off-Balance Sheet Arrangements

We do 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 and government-sponsored enterprise 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 at the same time 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 interest rates would have any significant impact on the realized value of our investment portfolio. If a 10% change in interest rates were to have occurred on September 30, 2014, 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 our Amended and Restated Term Loan Agreement is fixed and not subject to changes in market interest rates.

We do not have any foreign currency or other derivative financial instruments.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures 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 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 was 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 a particular design will succeed in achieving its stated goals under all potential future conditions. Furthermore, over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of September 30, 2014, 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, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2014.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter ended September 30, 2014, that have materially affected, or are reasonably likely to materially affect, the Company's 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.

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 Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2013.

If any of the following risks occur, our business, financial condition, results of operations or prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline and you might lose all or part of your investment. Additional risks and uncertainties of which we are currently unaware may also become important factors that affect us.

Risks Relating to Our Business and our Industry

We have incurred significant operating losses since inception and cannot assure you that we will achieve profitability.*

Since our inception in January 2006 we have incurred a significant net loss. As of September 30, 2014, we had an accumulated deficit of $230.2 million. To date, we have financed our operations primarily through sales of equity securities, debt financing with Capital Royalty Partners and certain of its affiliates, and sales of our products. We have devoted substantially all of our resources to the research and development of our products, the commercial launch of our products, the development of a sales and marketing team and the assembly of a management team to manage our business.

We began commercial sales of t:slim in the third quarter of 2012. Beginning in the first quarter of 2013, we have been able to manufacture and sell t:slim at a cost and in volumes sufficient to allow us to achieve a positive gross margin. For the year ended December 31, 2013, our gross profit was $6.2 million. However, although we have achieved a positive gross margin, we still operate at a substantial net loss and expect that we will continue to do so for at least the next several years.

To implement our business strategy we need to, among other things, grow our sales 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 only recently began to commercialize t:slim, 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.

We currently rely on sales of t:slim to generate a significant portion of our revenue, and any factors that negatively impact sales of this product may adversely affect our business, financial condition and operating results.

Our primary revenue-generating commercial product is t:slim, which we introduced to the market in the third quarter of 2012. We expect to continue to derive a significant portion of our revenue from the sale of t:slim and pump-related supplies. Accordingly, our ability to generate revenue is highly dependent on our ability to market and sell t:slim.

Sales of t:slim may be negatively impacted by many factors, including:

problems arising from the expansion of our manufacturing capabilities, or destruction, loss, or temporary shutdown of our manufacturing facility;

changes in reimbursement rates or policies relating to t:slim or similar products or technologies by third-party payors;

our inability to enter into contracts with third-party payors on a timely basis and on acceptable terms;

claims that t:slim, or any component thereof, infringes on patent rights or other intellectual property rights of third-parties;

the harm to our reputation or any other associated liability or perceived risks that may arise from our January 2014 recall of cartridges used with the t:slim; and

adverse regulatory or legal actions relating to t:slim or similar products or technologies.

Because we currently rely on a single product to generate a significant portion of our revenue, any factors that negatively impact sales of this product, or result in sales of this product increasing at a lower rate than expected, could adversely affect our business, financial condition and operating results and negatively impact our ability to successfully launch future products currently under development.

The failure of t:slim to achieve and maintain market acceptance could result in us achieving sales below our expectations, which would cause our business, financial condition and operating results to be materially and adversely affected.*

Our current business strategy is highly dependent on t:slim achieving and maintaining market acceptance. In order for us to sell t:slim to people with insulin-dependent diabetes, we must convince them, their caregivers and healthcare providers that it is an attractive alternative to competitive products for the treatment of diabetes, including traditional insulin pump products and MDI therapies, as well as alternative insulin treatment methodologies. Market acceptance and adoption of t:slim depends on educating people with diabetes, as well as their caregivers and healthcare providers, as to the distinct features, ease-of-use, positive lifestyle impact, and other perceived benefits of t:slim as compared to competitive products. If we are not successful in convincing existing and potential customers of the benefits of t:slim, or if we are not able to achieve the support of caregivers and healthcare providers for t:slim, our sales may decline or we may fail to increase our sales in line with our forecasts.

Achieving and maintaining market acceptance of t:slim could be negatively impacted by many factors, including:

the failure of t:slim to achieve wide acceptance among people with insulin-dependent diabetes, their caregivers, insulin-prescribing healthcare providers, third-party payors and key opinion leaders in the diabetes treatment community;

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

perceived risks associated with the use of t:slim or similar products or technologies generally;

the introduction of competitive products and the rate of acceptance of those products as compared to t:slim;

discounts or other financial incentives that our competitors may offer for competitive products;

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

In addition, t:slim may be perceived by people with insulin-dependent diabetes, their caregivers or healthcare providers to be more complicated, less reliable or less effective than traditional insulin therapies, including MDI, and people may be unwilling to change their current treatment regimens. These negative perceptions may be heightened following our January 2014 recall of cartridges used with the t:slim.

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

If t:slim does not achieve and maintain widespread market acceptance, we may fail to achieve sales at or above our projected amounts. If our sales do not meet projected amounts, we may fail to meet our strategic objectives, and our business, financial condition and operating results could be materially and adversely affected.

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

We have derived nearly all of our revenue from the sale of t:slim in the United States and expect to continue to do so until we are able to commercialize our other products that are currently under development. A substantial portion of the purchase price of an insulin pump is typically paid for by third-party payors, including private insurance companies, preferred provider organizations and other managed care providers. Future sales of our current and future products will be limited unless our customers can rely on third-party payors to pay for all or part of the associated purchase cost. Access to adequate coverage and reimbursement for our current and future products by third-party payors is essential to the acceptance of our products by customers.

Many third-party payors use coverage decisions and payment amounts determined by the Centers for Medicare and Medicaid Services, or CMS, which administers the U.S. Medicare program, as guidelines in setting their coverage and reimbursement policies. Medicare has recently begun to review its reimbursement practices for diabetes-related products. Medicare implemented a competitive bidding process for blood glucose strip reimbursement, which resulted in a significant reduction in the reimbursement rate for those products. More recently, Medicare has also initiated a competitive bidding process for insulin pumps in limited geographies. As a result, there is uncertainty as to the future Medicare reimbursement rate for our products. In addition, those third-party payors that do not follow the CMS guidelines may adopt different coverage and reimbursement policies for our current and future products. It is possible that some third-party payors will not offer any coverage for our current or future products.

We currently have contracts establishing reimbursement for t:slim with 78 national and regional third-party payors in the United States. While we anticipate entering into additional contracts with third-party payors, we cannot guarantee that we will succeed in doing so or that the reimbursement contracts that we are able to negotiate will enable us to sell our products on a profitable basis. In addition, contracts with third-party payors generally can be modified or terminated by the third-party payor without cause and with little or no notice to us. Moreover, compliance with the administrative procedures or requirements of third-party payors may result in delays in processing approvals by those third-party payors for customers to obtain coverage for t:slim. Failure to secure or retain adequate coverage or reimbursement for t:slim and our future products by third-party payors, or delays in processing approvals by those payors, could result in the loss of sales, which could have a material adverse effect on our business, financial condition and operating results.

Furthermore, the healthcare industry in the United States is increasingly focused on cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with third-party payors. If third-party payors deny coverage or reduce their current levels of payment, or if our production costs increase faster than increases in reimbursement levels, we may be unable to sell t:slim on a profitable basis.

We operate in a very competitive industry and if we fail to compete successfully against our existing or potential competitors, many of whom have greater resources than we have, our sales and operating results may be negatively affected.

The medical device industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products or technologies, or other activities of industry participants. t:slim competes directly with a number of traditional insulin pumps as well as other methods for the treatment of diabetes. Many of our existing and potential competitors are major medical device companies that are either publicly traded companies or divisions or subsidiaries of publicly traded companies. For instance, Medtronic MiniMed, a division of Medtronic, Inc., has been the market leader for many years and has the majority share of the traditional insulin pump market in the United States. Other significant insulin pump suppliers in the United States include Animas Corporation, a division of Johnson & Johnson, Roche Diagnostics, a division of F. Hoffman-La Roche Ltd., and Insulet Corporation.

These competitors also enjoy several competitive advantages over us, including:

greater financial and human resources for sales and marketing, and product development;

established relationships with healthcare providers and third-party payors;

established reputation and name recognition among healthcare providers and other key opinion leaders in the diabetes industry;

in some cases, an established base of long-time customers;

products supported by long-term clinical data;

larger and more established distribution networks;

greater ability to cross-sell products or provide incentives to healthcare providers to use their products; and

more experience in conducting research and development, manufacturing, clinical trials, and obtaining regulatory approval or clearance.

In some instances, our competitors also offer products that include features that we do not currently offer. For instance, Medtronic currently offers a traditional insulin pump that is integrated with a CGM system with a recently approved threshold suspend feature, and Insulet offers an insulin pump with a tubeless delivery system that does not utilize an infusion set. For these and other reasons, we may not be able to compete successfully against our current or potential future competitors. As a result, we may fail to meet our strategic objectives and forecasted budget, and our business, financial condition and operating results could be materially and adversely affected.

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

Our ability to achieve our strategic objectives will depend, among other things, on our ability to develop and commercialize products for the treatment of diabetes that offer distinct features, are easy-to-use, receive adequate coverage and reimbursement from third-party payors, and are more appealing than available alternatives. Our primary competitors, as well as a number of other companies, medical researchers and existing pharmaceutical companies are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs and other therapies for the monitoring, treatment and prevention of diabetes. Any technological breakthroughs in diabetes monitoring, treatment or prevention could reduce the potential market for t:slim or render t:slim obsolete altogether, which would significantly reduce our sales.

Because of the size of the insulin-dependent diabetes market, we anticipate that companies will continue to dedicate significant resources to developing competitive products. The frequent introduction by competitors of products that are or claim to be superior to our products may create market confusion that may make it difficult to differentiate the benefits of our products over competitive products. In addition, the entry of multiple new products has led some of our competitors to employ pricing strategies that could adversely affect the pricing of our products. If a competitor develops a product that competes with or is perceived to be superior to t:slim, or if competitors continue to utilize strategies that place downward pressure on pricing within our industry, our sales may decline significantly or may not increase in line with our forecasts, either of which would materially adversely affect our business, financial condition and operating results.

Moreover, we have designed our products to resemble modern consumer electronic devices to address certain embarrassment and functionality concerns consumers have raised with respect to traditional pumps. The consumer electronics industry is itself highly competitive, and characterized by continual new product introductions, rapid developments in technology, and subjective and changing consumer preferences. If, in the future, consumers cease to view our products as contemporary or convenient as compared to then-existing consumer electronics technology, our products may become less desirable.

If we are unable to expand our sales, marketing and clinical infrastructure effectively and on a timely basis, we may fail to increase our sales to meet our forecasts.*

Because we began commercialization of t:slim in the third quarter of 2012, we have only limited experience marketing and selling our products as well as training new customers on the use of t:slim. We derive nearly all of our revenue from the sale of t:slim and pump-related supplies and we expect that this will continue for the next several years unless and until we receive regulatory clearance or approval for other products currently in development. As a result, our financial condition and operating results are and will continue to be highly dependent on the ability of our sales representatives to adequately promote, market and sell t:slim and the ability of our diabetes educators to train new customers on the use of t:slim. If our sales and marketing representatives or diabetes educators fail to achieve their objectives, our sales could decrease or may not increase at levels that are in line with our forecasts.

A key element of our business strategy is the continued expansion of our sales, marketing and clinical infrastructure to drive adoption of our products, which includes our team of diabetes educators that trains new customers on the use of t:slim. We have rapidly increased the number of sales, marketing and clinical personnel employed by us since the initial commercial launch of t:slim. However, we have faced considerable challenges in quickly growing our sales, marketing and clinical force over the past 12-18 months, including with respect to recruiting, training and assimilation of new territories and accounts. We expect to continue to face significant challenges as we manage and grow our sales, marketing and clinical infrastructure and work to retain the individuals who make up those networks. If any of our sales, marketing or clinical representatives were to leave us, our sales could be adversely affected. If a sales, marketing or clinical representative were to depart and be retained by one of our competitors, we may fail to prevent them from helping competitors solicit business from our existing customers, which could further adversely affect our sales. In addition, if we are not able to recruit and retain a network of diabetes educators, we may not be able to successfully train new customers on the use of t:slim, which could delay new sales and harm our reputation.

As we increase our sales, marketing and clinical expenditures with respect to existing or planned products, we will need to further expand the reach of our sales, marketing and clinical networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled sales, marketing and clinical representatives with significant industry-specific knowledge in various areas, such as diabetes treatment techniques and technologies, as well as the competitive landscape for our products. Recently hired sales representatives require training and take time to achieve full productivity, and the overall expansion of our sales force also disrupts the productivity of our existing sales representatives. If we fail to train recent hires adequately, or if we experience high turnover in our sales force in the future, we cannot be certain that new hires will become as productive as may be necessary to maintain or increase our sales. In addition, the expansion of our sales, marketing and clinical personnel will continue to place significant burdens on our management team.

If we are unable to expand our sales, marketing and clinical capabilities, we may not be able to effectively commercialize our existing or planned products, or enhance the strength of our brand, either of which could result in the failure of our sales to increase in line with our forecasts.

Our sales and marketing efforts are dependent on independent distributors who are free to market products that compete with t:slim. If we are unable to maintain or expand our network of independent distributors, our sales may be negatively affected.*

For the nine months ended September 30, 2014, approximately 72% of our sales were generated through 35 independent distributors. While we expect that the percentage of our sales generated from independent distributors will decrease over time as we enter into contracts with additional third party payors, we believe that a meaningful percentage of our sales will continue to be generated by independent distributors for the foreseeable future and it is possible that the percentage of our sales generated from independent distributors could increase in the near term. None of our independent distributors has been required to sell our products exclusively and each of them may freely sell the products of our competitors. Our distributor agreements generally have one year initial terms with automatic one-year renewal terms, and are terminable in connection with a party’s material breach.

Some of our independent distributors account for a significant portion of our sales volume. For the nine months ended September 30, 2014, our two largest independent distributors comprised approximately 30% of our sales. If any of our key independent distributors were to cease to distribute our products, our sales could be adversely affected. In such a situation, we may need to seek alternative independent distributors or increase our reliance on our other independent distributors or our direct sales representatives, which may not prevent our sales from being adversely affected. Additionally, to the extent that we enter into additional arrangements with independent distributors to perform sales, marketing, or distribution services, the terms of the arrangements could cause our product margins to be lower than if we directly marketed and sold our products.

Our ability to maintain and grow our revenue depends in part on retaining a high percentage of our customer base.

A key to maintaining and growing our revenue is the retention of a high percentage of our customers due to the potentially significant revenue generated from ongoing purchases of disposable insulin cartridges. In addition, t:slim is designed and tested to remain effective for four years and a satisfied customer may consider purchasing another product from us when the time comes to replace the pump. We have developed retention programs aimed at customers, their caregivers and healthcare providers, which include training specific to t:slim, ongoing support by sales and clinical employees and 24/7 technical support and customer service. If demand for our products fluctuates as a result of the introduction of competitive products, changes in reimbursement policies, manufacturing problems, perceived safety or reliability issues with our or competitors' products, the failure to secure regulatory clearance or approvals, or for other reasons, our ability to attract and retain customers could be harmed. The failure to retain a high percentage of our customers would negatively impact our revenue growth and may have a material adverse effect on our business, financial condition and operating results.

If important assumptions about the potential market for our products are inaccurate, or if we have failed to understand what people with insulin-dependent diabetes are seeking in an insulin pump, our business and operating results may be adversely affected.

Our business strategy was developed based on a number of important assumptions about the diabetes industry in general, and the insulin-dependent diabetes market in particular, any one or more of which may prove to be inaccurate. For example, we believe that the benefits of insulin pump therapy as compared to other common insulin treatment alternatives will continue to drive growth in the market for insulin pump therapy. In addition, we believe the incidence of diabetes in the United States and worldwide is increasing rapidly. However, each of these trends is uncertain and limited sources exist to obtain reliable market data. The actual incidence of diabetes, and the actual demand for our products or competitive products, could differ materially from our projections if our assumptions are incorrect. In addition, our strategy of focusing exclusively on the insulin-dependent diabetes market may limit our ability to increase sales or achieve profitability.

Another key element of our business strategy is utilizing market research to understand what people with diabetes are seeking to improve their diabetes therapy management. This strategy underlies our entire product design, marketing and customer support approach and is the basis on which we developed t:slim. However, our market research is based on interviews, focus groups and online surveys involving people with insulin-dependent diabetes, their caregivers and healthcare providers that represent only a small percentage of the overall insulin-dependent diabetes market. As a result, the responses we received may not be reflective of the broader market and may not provide us accurate insight into the desires of people with insulin-dependent diabetes. In addition, understanding the meaning and significance of the responses received during our market research necessarily requires that analysis be conducted and conclusions be drawn. We may not be able perform an analysis that yields meaningful results, or the conclusions we draw from the analysis could be misleading. Moreover, even if our market research has allowed us to better understand the features consumers are seeking in an insulin pump to improve management of their diabetes therapy, there can be no assurance that consumers will actually purchase our products or that our competitors will not develop products with similar features.

We have a limited operating history and may face difficulties encountered by companies early in their commercialization in competitive and rapidly evolving markets.

We commenced operations in 2006 and began commercializing t:slim in the third quarter of 2012. Accordingly, we have a limited operating history upon which to evaluate our business and forecast our future sales and operating results. In assessing our business prospects, you should consider the various risks and difficulties frequently encountered by companies early in their commercialization in competitive and rapidly evolving markets, particularly companies that develop and sell medical devices. These risks include our ability to:

- implement and execute our business strategy;
- expand and improve the productivity of our sales and marketing infrastructure to grow sales of our existing and proposed products;
- increase awareness of our brand and build loyalty among people with insulin-dependent diabetes, their caregivers and healthcare providers;
- manage expanding operations;
- expand our manufacturing capabilities, including increasing production of current products efficiently while maintaining quality standards and adapting our manufacturing facilities to the production of new products;
- respond effectively to competitive pressures and developments;
- enhance our existing products and develop proposed products;

obtain and maintain regulatory clearance or approval to commercialize proposed products and enhance our existing products;

perform clinical trials with respect to our existing products and proposed products; and

attract, retain and motivate qualified personnel in various areas of our business.

Due to our limited operating history, we may not have the institutional knowledge or experience to be able to effectively address these and other risks that may face our business. In addition, we may not be able to develop insights into trends that could emerge and negatively affect our business and may fail to respond effectively to those trends. As a result of these or other risks, we may not be able to execute key components of our business strategy, and our business, financial condition and operating results may suffer.

Manufacturing risks may adversely affect our ability to manufacture products and could reduce our gross margins and negatively affect our operating results.

Our business strategy depends on our ability to manufacture our current and proposed products in sufficient quantities and on a timely basis so as to meet consumer demand, while adhering to product quality standards, complying with regulatory requirements and managing manufacturing costs. We are subject to numerous risks relating to our manufacturing capabilities, including:

quality or reliability defects in product components that we source from third party suppliers;

our inability to secure product components in a timely manner, in sufficient quantities or on commercially reasonable terms;

our failure to increase production of products to meet demand;

the challenge of implementing and maintaining acceptable quality systems while experiencing rapid growth;

our inability to modify production lines to enable us to efficiently produce future products or implement changes in current products in response to regulatory requirements;

difficulty identifying and qualifying alternative suppliers for components in a timely manner; and

potential damage to or destruction of our manufacturing equipment or manufacturing facility.

These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes. As demand for our products increases, we will have to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes and quality systems. If we fail to increase our production capacity efficiently while also maintaining quality requirements, our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline. In addition, although we expect some of our products in development to share product features and components with t:slim, manufacturing of these products may require the modification of our production lines, the hiring of specialized employees, the identification of new suppliers for specific components, or the development of new manufacturing technologies. It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable.

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

We rely on third-party suppliers to supply components of t:slim and of our potential future products. For example, we rely on plastic injection molding companies to provide plastic molded components, electronic manufacturing suppliers to provide electronic assemblies, and machining companies to provide machined mechanical components. For our business strategy to be successful, our suppliers must be able to provide us with components in sufficient quantities, in compliance with regulatory requirements and quality control standards, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. Increases in our product sales, whether forecasted or unanticipated, could strain the ability of our suppliers to deliver an increasingly large supply of components in a manner that meets these various requirements.

We do not have long-term supply agreements with most of our suppliers and, in many cases, we make our purchases on a purchase order basis. Under most of our supply agreements, we have no obligation to buy any given quantity of products, and our suppliers have no obligation to manufacture for us or sell to us any given quantity of products. As a result, our ability to purchase adequate quantities of our products may be limited. Additionally, our suppliers may encounter problems that limit their ability to manufacture products for us, including financial difficulties or damage to their manufacturing equipment or facilities. If we fail to obtain sufficient quantities of high quality components to meet demand on a timely basis, we could lose customer orders, our reputation may be harmed and our business could suffer.

We generally use a small number of suppliers for our products. Depending on a limited number of suppliers exposes us to risks, including limited control over pricing, availability, quality and delivery schedules. Moreover, due to the recent commercialization of our products and the limited amount of our sales to date, we do not have long-standing relationships with our manufacturers and may not be able to convince suppliers to continue to make components available to us unless there is demand for such components from their other customers. As a result, there is a risk that certain components could be discontinued and no longer available to us. We have in the past been, and we may in the future be, required to make significant “last time” purchases of component inventory that is being discontinued by the manufacturer to ensure supply continuity. If any one or more of our suppliers cease to provide us with sufficient quantities of components in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. Because of factors such as the proprietary nature of our products, our quality control standards and regulatory requirements, we cannot quickly engage additional or replacement suppliers for some of our critical components. Failure of any of our suppliers to deliver products at the level our business requires would limit our ability to meet our sales commitments, which could harm our reputation and could have a material adverse effect on our business.

We may also have difficulty obtaining similar components from other suppliers that are acceptable to FDA, or other regulatory agencies, and the failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination of distribution, product seizures or civil penalties. It could also require us to cease using the components, seek alternative components or technologies and modify our products to incorporate alternative components or technologies, which could result in a requirement to seek additional regulatory approvals. Any disruption of this nature or increased expenses could harm our commercialization efforts and adversely affect our operating results.

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

Our principal offices are presently located in four buildings in San Diego, California. Substantially all of our operations are conducted at this location, including our manufacturing processes, research and development activities, customer and technical support, and management and administrative functions. In addition, substantially all of our inventory of component supplies and finished goods is held at this location. We take precautions to safeguard our facilities, including acquiring insurance, employing back-up generators, adopting health and safety protocols and utilizing off-site storage of computer data. However, vandalism, terrorism or a natural or other disaster, such as an earthquake, fire or flood, could damage or destroy our manufacturing equipment or our inventory of component supplies or finished goods, cause substantial delays in our operations, result in the loss of key information, and cause us to incur additional expenses. Our insurance may not cover our losses in any particular case. In addition, regardless of the level of insurance coverage, damage to our facilities may have a material adverse effect on our business, financial condition and operating results.

If we do not enhance our product offerings through our research and development efforts, we may fail to effectively compete or become profitable.

In order to increase our sales and our market share in the insulin-dependent diabetes market, we must enhance and broaden our product offerings in response to the evolving demands of people with insulin-dependent diabetes and healthcare providers, as well as competitive pressures and technologies. We may not be successful in developing, obtaining regulatory approval for, or marketing our proposed products when anticipated, or at all. In addition, notwithstanding our market research efforts, our future products may not be accepted by consumers, their caregivers, healthcare providers or third-party payors who reimburse consumers for our products. The success of any proposed product offerings will depend on numerous factors, including our ability to:

identify the product features that people with insulin-dependent diabetes, their caregivers and healthcare providers are seeking in an insulin pump and successfully incorporate those features into our products;

develop and introduce proposed products in sufficient quantities and in a timely manner;

offer products at a price that is competitive with other products then available;

adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third-parties;

demonstrate the safety and efficacy of proposed products; and

obtain the necessary regulatory approvals for proposed products.

If we fail to generate demand by developing products that incorporate features requested by consumers, their caregivers or healthcare providers, or if we do not obtain regulatory clearance or approval for proposed products in time to meet market demand, we may fail to generate sales sufficient to achieve or maintain profitability. We have in the past experienced, and we may in the future experience, delays in various phases of product development and commercial launch, including during research and development, manufacturing, limited release testing, marketing and customer education efforts. Any delays in our anticipated regulatory submissions or approvals, or subsequent product launches, may significantly impede our ability to successfully compete in our markets. In particular, such delays could cause customers to delay or forego purchases of our products, or to purchase our competitors' products. Even if we are able to successfully develop proposed products when anticipated, these products may not produce sales in excess of the costs of development, and they may be quickly rendered obsolete by changing consumer preferences or the introduction by our competitors of products embodying new technologies or features.

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

The product we currently market in the United States received pre-market clearance under Section 510(k) of the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA. This process is shorter and typically requires the submission of less supporting documentation than other FDA approval processes and does not always require long-term clinical studies. As a result, we currently lack the breadth of published long-term clinical data supporting the safety and efficacy of our products and the benefits they offer that might have been generated in connection with other approval processes. For these reasons, people with insulin-dependent diabetes and healthcare providers may be slower to adopt or recommend our products, we may not have comparative data that our competitors have or are generating, third-party payors may not be willing to provide coverage or reimbursement for our products and we may be subject to greater regulatory and product liability risks. Further, future studies or clinical experience may indicate that treatment with our products is not superior to treatment with competitive products. Such results could slow the adoption of our products and significantly reduce our sales, which could prevent us from achieving our forecasted sales targets or achieving or sustaining profitability. Moreover, if future results and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to mandatory product recalls, suspension or withdrawal of FDA clearance or approval, significant legal liability or harm to our business reputation.

Any alleged illness or injury associated with any of our products or product recall may negatively impact our financial results and business prospects depending on the scope, degree of publicity, reaction of our customers, healthcare professionals, and collaborators, competitive reaction, and consumer attitudes overall. Even if such an allegation or product liability claim lacks merit, cannot be substantiated, is unsuccessful or is not fully pursued, the negative publicity surrounding any assertion that our products caused illness, injury or death could adversely affect our reputation with customers, healthcare professionals, and existing and potential collaborators, and could adversely affect our operating results and cause a decline in our stock price.

We may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships with third-parties that may not result in the development of commercially viable products or the generation of significant future revenues.*

In the ordinary course of our business, we may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships to develop proposed products and to pursue new markets. Proposing, negotiating and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenues and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with our current or future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborators' or our future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

For example, we have entered into a development and commercialization agreement with DexCom, which provides us a non-exclusive license to integrate the DexCom G4 PLATINUM Continuous Glucose Monitor with t:slim G4, which we have previously referred to as t:sensor, during the term of the agreement. This agreement runs until February 1, 2015, with automatic one-year renewals. The license granted covers the United States and other territories may be added from time to time. Subject to payments of certain of the non-terminating party's development expenses, the agreement may be terminated by either party without cause. Termination of this agreement could require us to redesign t:slim G4 and attempt to integrate an alternative CGM system into t:sensor, which would require significant development and regulatory activities that might delay the launch and commercialization of this product or, following its launch, might not be completed in time to prevent an interruption in the availability of t:sensor to our customers.

We may seek to grow our business through acquisitions of complementary products or technologies, and the failure to manage acquisitions, or the failure to integrate them with our existing business, could have a material adverse effect on our business, financial condition and operating results.

From time to time, we may consider opportunities to acquire other products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base, or advance our business strategies. Potential acquisitions involve numerous risks, including:

problems assimilating the acquired products or technologies;

issues maintaining uniform standards, procedures, controls and policies;

unanticipated costs associated with acquisitions;

diversion of management's attention from our existing business;

risks associated with entering new markets in which we have limited or no experience; and

increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters.

We have no current commitments with respect to any acquisition. We do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition.

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

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage sales and marketing data, accounting and financial functions, inventory management, product development tasks, research and development data, customer service and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, attacks by computer viruses or hackers, power losses, and computer system or data network failures. In addition, t:connect, our cloud-based data management application, is hosted by a third-party service provider whose security and information technology systems are subject to similar risks, and our t:slim Pumps and products currently in development contain software which could be subject to computer virus or hacker attacks or other failures.

The failure of our or our service providers' information technology systems or our pumps' software to perform as we anticipate or our failure to effectively implement new information technology systems could disrupt our entire operation or adversely affect our software products and could result in decreased sales, increased overhead costs, and product shortages, all of which could have a material adverse effect on our reputation, business, financial condition and operating results.

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

Our rapid growth has placed, and we expect that it will continue to place, a significant strain on our management team and on our financial resources. For example, between December 31, 2012 and December 31, 2013 our employee base has nearly doubled and we expect to continue to experience rapid growth of our employee base during 2014. Failure to manage our growth effectively could cause us to misallocate management or financial resources, and result in losses or weaknesses in our infrastructure, which could materially adversely affect our business. Additionally, our anticipated growth will increase the demands placed on our suppliers, resulting in an increased need for us to manage our suppliers and monitor for quality assurance. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our business objectives.

We depend on the knowledge and skills of our senior management and other key employees, and if we are unable to retain and motivate them or recruit additional qualified personnel, our business may suffer.

We have benefited substantially from the leadership and performance of our senior management, as well as certain key employees. For example, our chief executive officer, as well as other key members of management, have experience successfully scaling an early stage medical device company to achieve profitability. Our success will depend on our ability to retain our current management and key employees, and to attract and retain qualified personnel in the future. Competition for senior management and key employees in our industry is intense and we cannot guarantee that we will be able to retain our personnel or attract new, qualified personnel. The loss of the services of certain members of our senior management or key employees could prevent or delay the implementation and completion of our strategic objectives, or divert management's attention to seeking qualified replacements. Each member of senior management as well as our key employees may terminate employment without notice and without cause or good reason. The members of our senior management are not subject to non-competition agreements. Accordingly, the adverse effect resulting from the loss of certain members of senior management could be compounded by our inability to prevent them from competing with us.

In addition, the sale of our products is logistically complex, requiring us to maintain an extensive sales, marketing and clinical infrastructure consisting of sales representatives, clinical diabetes educators and customer support personnel. We face considerable challenges in recruiting, training, managing, motivating and retaining the members of these teams, including managing geographically dispersed efforts. These challenges are exacerbated by the fact that our strategic plan requires us to rapidly grow our sales, marketing and clinical infrastructure in order to generate demand for our products. If we fail to maintain and grow a dedicated team of sales and marketing and clinical personnel, we could fail to take advantage of an opportunity to enhance brand recognition and grow sales, and our business, financial condition and operating results could be adversely affected.

If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of federal and state laws protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services, or HHS, promulgated patient privacy rules under the HIPAA. These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. If we or any of our service providers are found to be in violation of the promulgated patient privacy rules under HIPAA, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and operating results.

Risks Related to our Financial Results and Need for Financing

We will need to generate significant sales to achieve profitable operations.

We intend to increase our operating expenses substantially in connection with the continued growth of our sales and marketing infrastructure, our ongoing research and development activities, the expansion of our manufacturing capabilities, and the commensurate development of our management team, administrative functions and facilities. We will need to generate significant sales to achieve profitability, and we might not be able to do so. Even if we do generate significant sales, we might not be able to achieve, sustain or increase profitability on a quarterly or annual basis in the future. If our sales grow more slowly than we have forecasted, or if our operating expenses exceed our expectations, our financial performance and results of operations will be adversely affected.

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

At September 30, 2014, we had $81.9 million in cash, cash equivalents and short term investments. We believe that our cash on hand, cash available under our term loan agreement and proceeds from the exercise of warrants and options will be sufficient to satisfy our liquidity requirements for at least the next 18 months. However, the continued growth of our business, including the expansion of our sales and marketing infrastructure, research and development activities, and manufacturing capabilities, will significantly increase our expenses. In addition, the amount of our future product sales is difficult to predict, especially in light of the recent commercialization of t:slim, and actual sales may not be in line with our forecasts. As a result, we may be required to seek additional funds in the future. Our future capital requirements will depend on many factors, including:

the revenue generated by sales of t:slim and any other future products that we may develop and commercialize;

the costs associated with expanding our sales and marketing infrastructure;

the expenses we incur in maintaining our manufacturing facility and adding further manufacturing equipment and capacity;

the cost associated with developing and commercializing our proposed products or technologies;

the cost of obtaining and maintaining regulatory clearance or approval for our current or future products;

the cost of ongoing compliance with regulatory requirements;

expenses we incur in connection with potential litigation or governmental investigations;

anticipated or unanticipated capital expenditures; and

unanticipated general and administrative expenses.

As a result of these and other factors, we do not know whether and the extent to which we may be required to raise additional capital. We may in the future seek additional capital from public or private offerings of our capital stock, borrowings under credit lines or other sources. If we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, we may incur significant financing costs, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaborations, licensing, joint ventures, strategic alliances, partnership arrangements or other similar arrangements, it may be necessary to relinquish valuable rights to our potential future products or proprietary technologies, or grant licenses on terms that are not favorable to us.

If we are unable to raise additional capital, we may not be able to expand our sales and marketing infrastructure, enhance our current products or develop new products, take advantage of future opportunities, or respond to competitive pressures, changes in supplier relationships, or unanticipated changes in customer demand. Any of these events could adversely affect our ability to achieve our strategic objectives, which could have a material adverse effect on our business, financial condition and operating results.

Our operating results may fluctuate significantly from quarter to quarter.

We began commercial sales of t:slim in the third quarter of 2012. Although we have a very limited operating history, there has been and there may continue to be meaningful variability in our operating results among quarters, as well as within each quarter. Our operating results, and the variability of these operating results, will be affected by numerous factors, including:

our ability to increase sales of t:slim and to commercialize and sell our future products, and the number of our products sold in each quarter;

acceptance of our products by people with insulin-dependent diabetes, their caregivers, healthcare providers and third-party payors;

the pricing of our products and competitive products, and the effect of third-party coverage and reimbursement policies;

our ability to establish and grow an effective sales and marketing infrastructure;

the amount of, and the timing of the payment for, insurance deductibles required to be paid by our customers and potential customers under their existing insurance plans;

interruption in the manufacturing or distribution of our products;

our ability to manufacture products that meet quality and reliability requirements;

seasonality and other factors affecting the timing of purchases of our products;

timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;

results of clinical research and trials on our existing and future products;

- the ability of our suppliers to timely provide us with an adequate supply of components that meet our requirements;
- regulatory clearance or approvals affecting our products or those of our competitors; and
- the timing of revenue recognition associated with our product sales pursuant to applicable accounting standards.

As a result of our limited operating history, and due to the complexities of the industry in which we operate, it will be difficult for us to forecast demand for our current or future products with any degree of certainty, which means it will be difficult for us to forecast our sales. In addition, we will be significantly increasing our operating expenses as we expand our business. Accordingly, we may experience substantial variability in our operating results from quarter to quarter, including unanticipated quarterly losses. If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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

As of March 31, 2014, we owed an aggregate principal amount of $30.0 million to Capital Royalty Partners pursuant to a term loan agreement under which we could borrow up to a total of $45.0 million under certain circumstances. In April 2014, we entered into an amended and restated term loan agreement with Capital Royalty Partners and their related affiliates. The amended and restated term loan agreement, among other things, amends the terms of the original term loan agreement to reduce the borrowing limit to $30.0 million. Concurrently, we also entered into a new term loan agreement with Capital Royalty Partners and their related affiliates, under which the Company may borrow up to an additional $30.0 million on or before March 31, 2015. Our ability to make scheduled payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected financial and operating performance. These amounts and our performance are subject to certain financial and business factors, as well as prevailing economic and competitive conditions, some of which may be beyond our control. We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. In addition, in the event of our breach of the term loan agreement with Capital Royalty Partners, we may not be allowed to draw additional amounts under the agreement, and we may be required to repay any outstanding amounts earlier than anticipated.

Our term loan agreements contain restrictive and financial covenants that may limit our operating flexibility.*

Our loan agreements with Capital Royalty Partners and Silicon Valley Bank contain certain restrictive covenants that limit our ability to incur additional indebtedness and liens, merge with other companies or consummate certain changes of control, acquire other companies, engage in new lines of business, make certain investments, pay dividends, transfer or dispose of assets, amend certain material agreements or enter into various specified transactions. We therefore may not be able to engage in any of the foregoing transactions unless we obtain the consent of the lenders or terminate the applicable loan agreement. Our term loan agreements also contain certain financial covenants, including minimum revenue and cash balance requirements, and financial reporting requirements. There is no guarantee that we will be able to generate sufficient cash flow or sales to meet the financial covenants or pay the principal and interest under our agreements. Furthermore, there is no guarantee that future working capital, borrowings or equity financing will be available to repay or refinance the amounts outstanding under a given agreement.

Prolonged negative economic conditions could adversely affect us, our customers and suppliers, which could harm our financial condition.

We are subject to the risks arising from adverse changes in general economic and market conditions. Uncertainty remains in the U.S. economy as it continues to recover from a severe economic recession. The U.S. economy continues to experience market volatility, difficulties in the financial services sector, diminished liquidity and availability of credit, reduced property values, concerns regarding inflation, increases in the cost of commodities, continuing high unemployment rates, reduced consumer spending and consumer confidence, and continuing economic uncertainties. The economic turmoil and the uncertainty about future economic conditions could negatively impact our existing and potential customers, adversely affect the financial ability of health insurers to pay claims, adversely impact our expenses and ability to obtain financing of our operations, and cause delays or other problems with key suppliers. We cannot predict the timing or impact of the recovery from this economic uncertainty.

Healthcare spending in the United States has been, and is expected to continue to be, negatively affected by the recent recession and continuing economic uncertainty. For example, patients who have lost their jobs or healthcare coverage may no longer be covered by an employer-sponsored health insurance plan, and patients reducing their overall spending may eliminate healthcare-related purchases. The recent recession and continuing economic uncertainty has also impacted the financial stability of many private health insurers. As a result, we believe that some insurers are scrutinizing insurance claims more rigorously and delaying or denying reimbursement more often. Since the sale of t:slim generally depends on the availability of third-party reimbursement, any delay or decline in reimbursement will adversely affect our sales.

Risks Related to our Intellectual Property and Potential Litigation

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

We rely primarily on patent, trademark and trade secret laws, as well as confidentiality and non-disclosure agreements, to protect our proprietary technologies. As of September 30, 2014, our patent portfolio consisted of approximately 31 issued U.S. patents and 53 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2021 and 2031. We are also seeking patent protection for our proprietary technology in other countries throughout the world. We also have nine pending U.S. trademark applications and 11 pending foreign trademark applications, as well as 13 trademark registrations, including four U.S. trademark registrations and nine foreign trademark registrations.

We have applied for patent protection relating to certain existing and proposed products and processes. Currently, five of our issued U.S. patents as well as various pending U.S. and foreign patent applications relate to the structure and operation of our pumping mechanism and are therefore particularly important to the functionality of our products. If we fail to timely file a patent application in any jurisdiction, we may be precluded from doing so at a later date. Furthermore, we cannot assure you that any of our patent applications will be approved in a timely manner or at all. The rights granted to us under our patents, and the rights we are seeking to have granted in our pending patent applications, may not be meaningful or provide us with any commercial advantage. In addition, those rights could be opposed, contested or circumvented by our competitors, or be declared invalid or unenforceable in judicial or administrative proceedings. The failure of our patents to adequately protect our technology might make it easier for our competitors to offer the same or similar products or technologies. Even if we are successful in receiving patent protection for certain products and processes, our competitors may be able to design around our patents or develop products that provide outcomes which are comparable to ours without infringing on our intellectual property rights. Due to differences between foreign and U.S. patent laws, our patented intellectual property rights may not receive the same degree of protection in foreign countries as they would in the United States. Even if patents are granted outside the United States, effective enforcement in those countries may not be available.

We rely on our trademarks and trade names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. We cannot assure you that our trademark applications will be approved in a timely manner or at all. Third-parties also may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote additional resources to marketing new brands. Further, we cannot assure you that competitors will not infringe upon our trademarks, or that we will have adequate resources to enforce our trademarks.

We have entered into confidentiality agreements and intellectual property assignment agreements with our officers, employees, temporary employees and consultants regarding our intellectual property and proprietary technology. In the event of unauthorized use or disclosure or other breaches of those agreements, we may not be provided with meaningful protection for our trade secrets or other proprietary information.

If a competitor infringes upon one of our patents, trademarks or other intellectual property rights, enforcing those patents, trademarks and other rights may be difficult and time consuming. Patent law relating to the scope of claims in the industry in which we operate is subject to rapid change and constant evolution and, consequently, patent positions in our industry can be uncertain. Even if successful, litigation to defend our patents and trademarks against challenges or to enforce our intellectual property rights could be expensive and time consuming and could divert management’s attention from managing our business. Moreover, we may not have sufficient resources or desire to defend our patents or trademarks against challenges or to enforce our intellectual property rights. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third-parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events may have a material adverse effect on our business, financial condition and operating results.

The medical device industry is characterized by patent litigation, and from time to time we may be subject to litigation that could be costly, result in the diversion of management's time and efforts, or require us to pay damages.*

Our success will depend in part on not infringing the patents or violating the other proprietary rights of third-parties. Significant litigation regarding patent rights exists in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make and sell our products. The large number of patents, the rapid rate of new patent issuances, and the complexities of the technology involved increase the risk of patent litigation.

From time to time we receive communications from third parties alleging our infringement of their intellectual property rights. Any intellectual property dispute or litigation could force us to do one or more of the following:

stop selling our products or using technology that contains the allegedly infringing intellectual property;

incur significant legal expenses;

pay substantial damages to the party whose intellectual property rights we are allegedly infringing;

redesign those products that contain the allegedly infringing intellectual property; or

attempt to obtain a license to the relevant intellectual property from third-parties, which may not be available on reasonable terms or at all.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. Further, as the number of participants in the diabetes market increases, the possibility of intellectual property infringement claims against us increases.

We may be subject to damages resulting from claims that we, or our employees, have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees were previously employed at other medical device companies, including those that are our direct competitors or could potentially be our direct competitors. In some cases, those employees joined our company recently. We may be subject to claims that we, or our employees, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to allegations that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we successfully defend against these claims, litigation could cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. We cannot guarantee that this type of litigation will not continue, and any future litigation or the threat thereof may adversely affect our ability to hire additional direct sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize proposed products, which could have an adverse effect on our business, financial condition and operating results.

We may incur product liability losses, and insurance coverage may be inadequate or unavailable to cover these losses.

Our business exposes us to potential product liability claims that are inherent in the design, manufacture, testing and sale of medical devices. We could become the subject of product liability lawsuits alleging that component failures, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition, injury or death to customers. The risk of one or more product liability claims or lawsuits may be even greater following our January 2014 voluntary recall of cartridges used with the t:slim Pump. In addition, the misuse of our products or the failure of customers to adhere to operating guidelines could cause significant harm to customers, including death, which could result in product liability claims. Product liability lawsuits and claims, safety alerts or product recalls, with or without merit, could cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, harm our reputation and adversely affect our ability to attract and retain customers, any of which could have a material adverse effect on our business, financial condition and operating results.

Although we maintain third-party product liability insurance coverage, it is possible that claims against us may exceed the coverage limits of our insurance policies. Even if any product liability loss is covered by an insurance policy, these policies typically have substantial deductibles for which we are responsible. Product liability claims in excess of applicable insurance coverage could have a material adverse effect on our business, financial condition and operating results. In addition, any product liability claim brought against us, with or without merit, could result in an increase of our product liability insurance premiums. Insurance coverage varies in cost and can be difficult to obtain, and we cannot guarantee that we will be able to obtain insurance coverage in the future on terms acceptable to us or at all. Our inability to obtain sufficient insurance coverage to protect again potential product liability claims could prevent or limit our commercialization of current products or products currently under development.

Risks Related to our Legal and Regulatory Environment

Our products and operations are subject to extensive governmental regulation, and failure to comply with applicable requirements could cause our business to suffer.

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state regulatory agencies. The regulations are very complex and are subject to rapid change and varying interpretations. Regulatory restrictions or changes could limit our ability to carry on or expand our operations or result in higher than anticipated costs or lower than anticipated sales. The FDA and other U.S. governmental agencies regulate numerous elements of our business, including:

product design and development;

pre-clinical and clinical testing and trials;

product safety;

establishment registration and product listing;

labeling and storage;

marketing, manufacturing, sales and distribution;

pre-market clearance or approval;

servicing and post-market surveillance;

advertising and promotion; and

recalls and field safety corrective actions.

Before we can market or sell a new regulated product or a significant modification to an existing product in the United States, we must obtain either clearance under Section 510(k) of the FDCA or approval of a PMA application from the FDA, unless an exemption from pre-market review applies. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based on extensive data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time-consuming, and we may not be able to obtain these clearances or approvals on a timely basis, or at all for our proposed products.

We received pre-market clearance for t:slim under Section 510(k) of the FDCA in November 2011. We obtained 510(k) clearance for t:connect in February 2013. From time to time, we make modifications to these products that may require a new 510(k). If the FDA requires us to go through a more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline or to not increase in line with our forecasts. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain PMA process.

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

we may not be able to demonstrate that our products are safe and effective for their intended users;

the data from our clinical trials may be insufficient to support clearance or approval; and

the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared or approved products on a timely basis.

Any delay in, or failure to receive or maintain, clearance or approval for our products under development could prevent us from generating revenue from these products or achieving profitability. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some customers from using our products and adversely affect our reputation and the perceived safety and efficacy of our products.

Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as fines, civil penalties, injunctions, warning letters, recalls of products, delays in the introduction of products into the market, refusal of the FDA or other regulators to grant future clearances or approvals, and the suspension or withdrawal of existing approvals by the FDA or other regulators. Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and operating results.

Furthermore, we may evaluate international expansion opportunities in the future. If we expand our operations outside of the United States, we will become subject to various additional regulatory and legal requirements under the applicable laws and regulations of the international markets we enter. These additional regulatory requirements may involve significant costs and expenditures and, if we are not able comply any such requirements, our international expansion and business could be significantly harmed.

Modifications to our products may require new 510(k) clearances or pre-market approvals, or may require us to cease marketing or recall the modified products until clearances are obtained.

Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, requires a new 510(k) clearance or, possibly, a

PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary for changes that we have made to our products. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMAs for modifications to our previously cleared or approved products for which we previously concluded that new clearances or approvals were not necessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Furthermore, the FDA's ongoing review of the 510(k) program may make it more difficult for us to modify our previously cleared products, either by imposing stricter requirements on when a new 510(k) for a modification to a previously cleared product must be submitted, or applying more onerous review criteria to such submissions.

If we or our third-party suppliers fail to comply with the FDA's good manufacturing practice regulations, this could impair our ability to market our products in a cost-effective and timely manner.

We and our third-party suppliers are required to comply with the FDA's Quality System Regulation, or QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. The FDA audits compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may impose inspections or audits at any time. If we or our suppliers have significant non-compliance issues or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action against us. Any of the foregoing actions could have a material adverse effect on our reputation, business, financial condition and operating results.

A recall of our products, or the discovery of serious safety issues with our products, could have a significant negative impact on us.*

The FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us, one of our distributors or any of our other third party suppliers could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any products that we distribute would divert managerial and financial resources and have an adverse effect on our reputation, financial condition and operating results, which could impair our ability to produce our products in a cost-effective and timely manner.

Further, under the FDA's medical device reporting, or MDR, regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner and have an adverse effect on our reputation, financial condition and operating results.

In January 2014, we implemented a voluntary recall of select lots of cartridges used with the t:slim that may be at risk of leaking. A cartridge leak could potentially result in the delivery of too much or too little insulin, which could lead to unexpected high or low blood glucose levels. Too much insulin can result in severe low blood sugar, or hypoglycemia, and too little insulin can lead to severe high blood sugar, or hyperglycemia, both of which can lead to serious injury or death. We notified the FDA of the recall and also notified our customers and any of our independent distributors that may have received affected cartridges. We have also filed multiple MDRs with the FDA following the recall and we expect to file additional MDRs in the future as we collect additional information.

Any adverse event involving any products that we distribute could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

Our failure to comply with U.S. federal and state fraud and abuse laws, including anti-kickback laws and other U.S. federal and state anti-referral laws, could have a material, adverse impact on our business.

There are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws. Our relationships with healthcare providers and other third-parties are subject to scrutiny under these laws. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state healthcare programs, including the

Medicare, Medicaid and Veterans Administration health programs.

Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include:

- the federal healthcare programs' Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

- the federal HIPAA of 1996, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

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

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

Further, the recently enacted Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Affordability Reconciliation Act, or, collectively, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity can now be found guilty under the PPACA without actual knowledge of the statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of those prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, financial condition and operating results.

To enforce compliance with the federal laws, the U.S. Department of Justice, or DOJ, has recently increased its scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time- and resource-consuming and can divert management's attention from our core business. Additionally, if a healthcare company settles an investigation with the DOJ or other law enforcement agencies, we may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal or state regulatory authorities might challenge our current or future activities under these laws. Any of these challenges could have a material adverse effect on our reputation, business, financial condition and operating results. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive.

We may be liable if we engage in the off-label promotion of our products.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of the off-label use of our products. Healthcare providers may use our products off-label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could result in substantial damage awards against us and harm our reputation.

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

Recent political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. The sales of our products depend in part on the availability of coverage and reimbursement from third-party payors such as government health administration authorities, private health insurers, health maintenance organizations and other healthcare-related organizations. Both the Federal and state governments in the United States continue to propose and pass new legislation and regulations designed to contain or reduce the cost of healthcare. This legislation and regulation may result in decreased reimbursement for medical devices, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices. This could harm our ability to market our products and generate sales.

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

Federal and state governments in the United States have recently enacted legislation to overhaul the nation’s healthcare system. While the goal of healthcare reform is to expand coverage to more individuals, it also involves increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. The PPACA substantially changes the way healthcare is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services and significantly impacts the medical device industries. Among other things, the PPACA:

establishes a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research;

implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and

creates an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. Most recently, on August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year which commenced in 2013. The uncertainties regarding the ultimate features of the PPACA and other healthcare reform initiatives and their enactment and implementation may have an adverse effect on our customers’ purchasing decisions regarding our products. In the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products. Cost control initiatives could decrease the price that we receive for our products. At this time, we cannot predict which, if any, additional healthcare reform proposals will be adopted, when they may be adopted or what impact they, or the PPACA, may have on our business and operations, and any of these impacts may be adverse on our operating results and financial condition.

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

The PPACA imposes, among other things, an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States beginning in 2013. Under these provisions, the Congressional Research Service predicts that the total cost to the medical device industry may be up to $20 billion over the next decade. We do not believe that t:slim is currently subject to this tax based on the retail exemption under applicable Treasury Regulations. However, the availability of this exemption is subject to interpretation by the IRS, and the IRS may disagree with our analysis. In addition, future products that we manufacture, produce or import may be subject to this tax. The financial impact this tax may have on our business is unclear and there can be no assurance that our business will not be materially adversely affected by it.

Risks Related to our Common Stock

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

Based on an aggregate of 23,491,770 shares of our common stock outstanding as of September 30, 2014, our executive officers and directors, and their affiliates owned, in the aggregate, over 50% of the voting power of our outstanding common stock. These persons, acting together, will have the ability to significantly influence or determine the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation, or sale of all or substantially all of our assets.

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

delaying, deferring or preventing a change in control of our company;

impeding a merger, consolidation, takeover or other business combination involving our company; or

causing us to enter into transactions or agreements that are not in the best interests of all stockholders.

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

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

authorize the issuance of preferred stock with powers, preferences and rights that may be senior to our common stock, which can be created and issued by the board of directors without prior stockholder approval;

provide for the adoption of a staggered board of directors whereby the board is divided into three classes each of which has a different three-year term;

provide that the number of directors shall be fixed by the board;

prohibit our stockholders from filling board vacancies;

provide for the removal of a director only with cause and then by the affirmative vote of the holders of a majority of the outstanding shares;

prohibit stockholders from calling special stockholder meetings;

prohibit stockholders from acting by written consent without holding a meeting of stockholders;

require the vote of at least two-thirds of the outstanding shares to approve amendments to the certificate of incorporation or bylaws; and

require advance written notice of stockholder proposals and director nominations.

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

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

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

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

As of December 31, 2013, we have federal net operating loss, or NOL, carryforwards of approximately $119.7 million. In general, if there is an “ownership change” with respect to our company, as defined under Section 382 of the Internal Revenue Code of 1986, as amended, which we refer to as the Code, the utilization of our NOL carryforwards may be subject to substantial limitations imposed by the Code, and similar state provisions. In general, an ownership change occurs whenever there is a shift in ownership of our company by more than 50% by one or more 5% stockholders over a specified time period. We updated our Section 382/383 analysis, from January 1, 2012 through December 31, 2013, regarding the limitation of the net operating losses and research and development credits. Based upon the analysis, we determined that no ownership changes occurred during that period. However, previous analysis determined that ownership changes have occurred in years prior to 2012, but will not have a material impact on the future utilization of such carryforwards. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. Accordingly, if we earn net taxable income, our ability to use net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increases in our future tax liabilities.

We do not intend to pay cash dividends.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, pursuant to the term loan agreement with Capital Royalty Partners, we are precluded from paying any cash dividends. Accordingly, you may have to sell some or all of your shares of our common stock in order to generate cash flow from your investment. You may not receive a gain on your investment when you sell shares and you may lose the entire amount of the investment.

The requirements of being a public company will increase our costs and may strain our resources and divert management’s attention.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the listing requirements of The NASDAQ Stock Market and other applicable securities rules and regulations. Compliance with these rules and regulations has increased and will continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly, and increase demand on our systems and resources.

The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Recent legislation permits “emerging growth companies” to implement many of these requirements over a longer period and up to five years from the end of our last fiscal year. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses.

In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management’s attention may be diverted from other business concerns, which could harm our business and operating results. Although we have hired additional employees to help us comply with these requirements, in the future we may need to hire more employees or utilize external consultants in order to further support our efforts, which will increase our expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, as well as an increase in stockholder activism, are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. New or changing laws, regulations and standards in particular are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new or evolving laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Moreover, as a public company that is subject to these rules and regulations, we may find it more difficult and more expensive for us to obtain certain types of insurance, and in particular director and officer liability insurance. We may be required to incur substantial costs to maintain our current levels of such coverage on acceptable terms.

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

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

not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;

less extensive disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and

exemptions from the requirements to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We intend to take advantage of these exemptions but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, which could result in a reduction in the price of our common stock.

Pursuant to the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting for so long as we are an “emerging growth company.”

Under existing SEC rules and regulations, we will be required to disclose changes made in our internal control over financial reporting on a quarterly basis and management will be required to assess the effectiveness of our controls annually. However, under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 until we are no longer an “emerging growth company.” We could be an “emerging growth company” for up to five years.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.*

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404(a) of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm conducted in connection with Section 404(b) of the Sarbanes-Oxley Act after we no longer qualify as an “emerging growth company,” may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We are required to disclose changes made in our internal control procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an “emerging growth company” under the recently enacted JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We could be an “emerging growth company” for up to five years. An independent assessment of the effectiveness of our internal controls could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

The price of our common stock might fluctuate significantly.

Prior to our recently completed initial public offering, there was no public market for our common stock. The trading price of our common stock is likely to be volatile for the foreseeable future. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

actual or anticipated fluctuations in our quarterly financial and operating results;

perceptions about the market acceptance of our products and the recognition of our brand;

overall performance of the equity markets;

introduction of proposed products, or announcements of significant contracts, licenses or acquisitions, by us or our competitors;

legislative, political or regulatory developments;

issuance of securities analysts' reports or recommendations;

additions or departures of key personnel;

threatened or actual litigation and government investigations;

sale of shares of our common stock by us or members of our management; and

general economic conditions.

These and other factors might cause the market price of our common stock to fluctuate substantially, which may negatively affect the liquidity of our common stock. In addition, in recent years, the stock market has experienced significant price and volume fluctuations. This volatility has had a significant impact on the market price of securities issued by many companies across many industries. The changes frequently appear to occur without regard to the operating performance of the affected companies. Accordingly, the price of our common stock could fluctuate based upon factors that have little or nothing to do with our company, and these fluctuations could materially reduce our share price.

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

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

Sales of our common stock, or the perception in the market that the holders of a large number of our shares intend to sell such shares, could reduce the market price of our common stock which would impair our ability to raise future capital through the sale of additional equity securities. We had outstanding 23,491,770 shares of common stock as of September 30, 2014, of which approximately 12,127,347 shares are restricted securities that may be sold only in accordance with the resale restrictions under Rule 144 of the Securities Act. In addition, as of September 30, 2014, we had outstanding options to purchase 4,899,528 shares of common stock and warrants to purchase 1,006,577 shares of common stock that, if exercised, will result in these additional shares becoming available for sale. As of September 30, 2014, there are also an aggregate of 2,808,965 shares of our common stock reserved for future grant or issuance under our 2013 Equity Incentive Plan and Employee Stock Purchase Plan.

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

In the future, we also may issue our securities if we need to raise additional capital. The number of new shares of our common stock issued in connection with raising additional capital could constitute a material portion of the then-outstanding shares of our common stock.

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-191601) which was declared effective by the SEC on November 13, 2013. On November 14, 2013, additional shares of our common stock were registered through a Registration Statement on Form S-1 (File No. 333-192324) filed pursuant to Rule 462(b) under the Securities Act. On November 19, 2013, a total of 8,000,000 shares of common stock were sold on our behalf at the initial public offering price of $15.00 per share, for aggregate gross offering proceeds of $120.0 million, managed by BofA Merrill Lynch and Piper Jaffray. In addition, on November 19, 2013, in connection with the exercise of the underwriters' over-allotment option, 1,200,000 additional shares of common stock were sold on our behalf at the initial public offering price of $15.00 per share, for aggregate gross offering proceeds of $18 million. We paid to the underwriters underwriting discounts totaling approximately $9.7 million in connection with the offering. In addition, we incurred additional costs of approximately $3.3 million in connection with the offering, which when added to the underwriting discounts paid by us, amounts to total costs of approximately $13.0 million. As a result, the net offering proceeds to us, after deducting underwriting discounts and offering expenses, were approximately $125.0 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

The net proceeds from the offering have been invested in money market funds and highly-liquid, highly-rated securities. We also estimate that we have used approximately $49.4 million to expand and support our sales and marketing infrastructure, approximately $19.5 million to fund research and development activities, and approximately $24.1 million to expand and support our manufacturing capabilities.

We intend to use the remainder of the net proceeds from the IPO for working capital expenditures and other general corporate purposes, including costs and expenses associated with being a public company. The amounts and timing of our actual use of the remaining proceeds will vary depending on numerous factors, including the factors described under the section entitled "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q. As a result, management will retain broad discretion over the allocation of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Footnote	Exhibit Number	Description of Document
(1)	3.1	Amended and Restated Certificate of Incorporation as currently in effect.
(1)	3.2	Amended and Restated Bylaws as currently in effect.
	31.1	Certification of Kim D. Blickenstaff, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

	31.2	Certification of John Cajigas, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
*	32.1	Certification of Kim D. Blickenstaff, Chief Executive Officer, pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
*	32.2	Certification of John Cajigas, Chief Financial Officer, pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
	101.INS	XBRL Instance Document.
	101.SCH	XBRL Taxonomy Extension Schema Document.
	101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
	101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
	101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
	101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

(1) Filed as an exhibit to the registrant's Registration Statement on Form S-1 (File No. 333-191601) and incorporated herein by reference.

* This certification shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to Section 18 of the Exchange Act. Such certification shall not be deemed to be incorporated by reference under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

SIGNATURES

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

	Tandem Diabetes Care, Inc.
Dated: November 6, 2014	By: /s/ Kim D. Blickenstaff Kim D. Blickenstaff President, Chief Executive Officer and Director (on behalf of the registrant and as the registrant's Principal Executive Officer)
	By: /s/ John Cajigas John Cajigas Chief Financial Officer and Treasurer (on behalf of the registrant and as the registrant's Principal Financial and Accounting Officer)

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