TANDEM DIABETES CARE INC
Form 10-Q
October 26, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Quarterly Period Ended September 30, 2017

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Transition Period from to

Commission File Number 001-36189

Tandem Diabetes Care, Inc.

(Exact name of registrant as specified in its charter)

Delaware	20-4327508
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
11045 Roselle Street	
San Diego, California	92121
(Address of principal executive offices)	(Zip Code)

(858) 366-6900

Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of October 23, 2017, there were 10,118,659 shares of the registrant's Common Stock outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

TANDEM DIABETES CARE, INC.

CONDENSED BALANCE SHEETS

(In thousands, except par value)

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

Accumulated other comprehensive loss	-	(1)
Accumulated deficit	(466,207)	(404,580)
Total stockholders' deficit	(27,958)	(5,927)
Total liabilities and stockholders' deficit	$ 87,977	$ 112,392

See accompanying notes to unaudited condensed financial statements.

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

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TANDEM DIABETES CARE, INC.

CONDENSED STATEMENTS OF OPERATIONS and comprehensive loss

(Unaudited)

(In thousands, except per share data)

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

See accompanying notes to unaudited condensed financial statements.

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

TANDEM DIABETES CARE, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

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

Supplemental disclosures of cash flow information		
Interest paid	$5,871	$3,205
Supplemental schedule of noncash investing and financing activities		
Lease incentive - lessor-paid tenant improvements	$3,037	$—
Debt discount included in other long-term liabilities	$4,116	$454
Common stock warrants issued in connection with term loan	$3,331	$—
Property and equipment included in accounts payable	$72	$802

See accompanying notes to unaudited condensed financial statements.

TANDEM DIABETES CARE, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

1. Organization and Basis of Presentation

The Company

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

The Company manufactures and sells insulin pump products in the United States that are designed to address large and differentiated needs of the insulin-dependent diabetes market. The Company’s pump products currently include:

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

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

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

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

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

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

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

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

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

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

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

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

Basis of Presentation

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

Interim financial results are not necessarily indicative of results anticipated for the full year or any other period(s). These unaudited condensed financial statements should be read in conjunction with the Company's audited financial statements and accompanying footnotes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016 ("Annual Report"), from which the balance sheet information herein was derived. These unaudited condensed financial statements exclude disclosures required by U.S. GAAP for complete financial statements.

2. Summary of Significant Accounting Policies

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

Use of Estimates

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

Restricted Cash

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

Accounts Receivable

The Company grants credit to various customers in the normal course of business. The Company maintains an allowance for doubtful accounts for potential credit losses. Provisions are made based on historical experience, assessment of specific risk, specific review of outstanding invoices, and various additional assumptions and estimates that are believed to be reasonable under the circumstances. Uncollectible accounts are written off against the allowance after appropriate collection efforts have been exhausted and when it is deemed that a balance is uncollectible.

Fair Value of Financial Instruments

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

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

Revenue Recognition

Revenue is generated primarily from sales in the United States of insulin pumps, disposable cartridges and infusion sets to individual customers and third-party distributors that resell the product to insulin-dependent diabetes customers. The Company is paid directly by customers who use the products, distributors and third-party insurance payors.

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

Trade-In Rights

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

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

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

Revenue Recognition for Arrangements with Multiple Deliverables

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

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

Product Returns

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

Warranty Reserve

The Company generally provides a four-year warranty on its insulin pumps to end user customers and may replace any pumps that do not function in accordance with the product specifications. Insulin pumps returned to the Company may be refurbished and redeployed. Additionally, the Company offers a six-month warranty on disposable cartridges and infusion sets. Estimated warranty costs are recorded at the time of shipment. Warranty costs are estimated based on the current expected product replacement cost and expected replacement rates based on historical experience. The Company evaluates the reserve quarterly and makes adjustments when appropriate. Changes to the actual replacement rates or the expected product replacement cost could have a material impact on the Company's warranty reserve.

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

Balance at December 31, 2016	$5,690
Provision for warranties issued during the period	