

TANDEM DIABETES CARE INC

FORM 8-K (Current report filing)

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Address	11045 ROSELLE STREET SUITE 200 San Diego, CA 92121
Telephone	858-366-6900
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SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment, Supplies & Distribution
Sector	Healthcare
Fiscal Year	12/31

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 27, 2017

Tandem Diabetes Care, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36189
(Commission
File Number)

20-4327508
(I.R.S. Employer
Identification No.)

11045 Roselle Street, San Diego, CA
(Address of principal executive offices)

92121
(Zip Code)

Registrant's telephone number, including area code: (858) 366-6900

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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.

Item 2.02 Results of Operations and Financial Condition.

On April 27, 2017, we issued a press release reporting our financial results for the quarter ended March 31, 2017. This press release has been furnished as Exhibit 99.1 to this report and is incorporated herein by this reference.

The information under this Item 2.02 and Exhibit 99.1 hereto is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Number</u>	<u>Description</u>
99.1	Press release of Tandem Diabetes Care, Inc. dated April 27, 2017 .

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 hereunto duly authorized.

Date: April 27, 2017

Tandem Diabetes Care, Inc.

/s/ David B. Berger

David B. Berger

Executive Vice President, General Counsel and Secretary

INDEX TO EXHIBITS

<u>Number</u>	<u>Description</u>
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FOR IMMEDIATE RELEASE**Tandem Diabetes Care Reports First Quarter 2017 Financial Results**

San Diego, April 27, 2017 – Tandem Diabetes Care®, Inc. (NASDAQ: TNDM), a medical device company and manufacturer of the only touchscreen insulin pumps available in the United States, today reported its financial results for the quarter ended March 31, 2017.

“Our first quarter results were highlighted by our sales performance, recognition of our #1 customer support services for the 4th consecutive year*, and meaningful progress with our new products in development,” said Kim Blickenstaff, President and Chief Executive Officer of Tandem Diabetes Care. “These achievements give us confidence in our ability to accomplish our key goals for this year, and we remain focused on successfully executing our business plan and supporting our growing customer base.”

In July 2016, the Company began offering eligible customers a Technology Upgrade Program to provide a pathway to ownership of the new t:slim X2™ Insulin Pump, which launched in October 2016. As previously announced, because of the accounting treatment of this program, the Company is now providing selected financial results on both a GAAP and non-GAAP basis.

Sales and Pump Shipments ¹

(in millions)	Three Months Ended March 31,	
	2017	2016
GAAP sales	\$ 19.0	\$ 20.1
Impact of Technology Upgrade Program	(1.5)	—
Non-GAAP sales ¹	<u>\$ 17.5</u>	<u>\$ 20.1</u>
Pump shipments	<u>2,816</u>	<u>4,042</u>

- 1) GAAP sales are determined in accordance with U.S. Generally Accepted Accounting Principles. Non-GAAP sales are adjusted for the impact of the Technology Upgrade Program. See the information under the heading “Use of Non-GAAP Financial Measures” in this press release, as well as under the heading “Reconciliation of GAAP versus Non-GAAP Financial Results” in the attached Press Release Exhibit.

* dQ&A USA Connections Surveys 2013 – 2016

First Quarter 2017 GAAP Results

The Company operated in a highly competitive environment in the first quarter of 2017. A total of 2,816 pumps were shipped in the quarter, down 30% from the 4,042 pumps shipped in the same period of 2016. Sales and gross margin in the first quarter of 2017 benefited from a strong continuation of customer interest in the t:slim G4, the Company's first insulin pump featuring continuous glucose monitoring integration, which was launched in September 2015. GAAP sales declined 5 percent to \$19.0 million for the quarter ended March 31, 2017 compared to \$20.1 million for the same period of 2016. Gross margin for the quarter ended March 31, 2017 was 36 percent compared to 35 percent for the same period of 2016.

For the first quarter of 2017, operating expenses totaled \$28.0 million compared to \$26.2 million for the same period of 2016. GAAP operating loss for the first quarter of 2017 was \$21.2 million, compared to \$19.2 million for the same period of 2016. GAAP operating margin for the first quarter of 2017 was negative 112 percent compared to negative 96 percent in the same period last year. Both operating loss and operating margin for the first quarter of 2017 included non-cash charges for stock-based compensation of \$3.0 million and depreciation and amortization of \$1.4 million for the first quarter of 2017, compared to stock-based compensation of \$2.8 million and depreciation and amortization of \$1.3 million for the comparable period of 2016.

First Quarter 2017 Non-GAAP Results

Non-GAAP sales, which are adjusted for the impact of the Technology Upgrade Program, declined 13 percent to \$17.5 million for the quarter ended March 31, 2017 compared to \$20.1 million for 2016. Non-GAAP gross margin for the quarter ended March 31, 2017 was 35 percent, adjusted for the impact of the Technology Upgrade Program, compared to 35 percent for the same period of 2016. Like the Company's GAAP results, non-GAAP sales and gross margin in the first quarter of 2017 were impacted by a highly competitive environment for the Company's products. Non-GAAP sales and gross margin in the first quarter of 2016 also benefited from continued post-launch interest in the t:slim G4 Pump.

For the first quarter of 2017, non-GAAP operating expenses totaled \$28.0 million compared to \$26.2 million for the same period of 2016. Non-GAAP operating loss for the first quarter of 2017 was \$21.9 million, compared to \$19.2 million for the same period of 2016. Non-GAAP operating margin for the first quarter was negative 126 percent compared to negative 96 percent in the same period of 2016. Both non-GAAP operating loss and operating margin included non-cash charges for stock-based compensation of \$3.0 million and depreciation and amortization of \$1.4 million for the first quarter of 2017, compared to stock-based compensation of \$2.8 million and depreciation and amortization of \$1.3 million for the comparable period of 2016.

Cash Balance and Liquidity

As of March 31, 2017, the Company had \$54.0 million in cash, cash equivalents, short-term investments and restricted cash.

2017 Guidance

The Company is reaffirming its annual financial guidance on a non-GAAP basis. It is difficult to estimate or predict the Company's GAAP financial results because it is difficult to estimate or predict the timing and rate of customer utilization of the Technology Upgrade Program. As a result, it is not currently possible for the Company to provide GAAP financial guidance, or to provide a reconciliation of GAAP guidance to non-GAAP guidance, with any degree of certainty. In the future, the Company expects to continue to provide its operating results on both a GAAP and non-GAAP basis. For additional information regarding the Technology Upgrade Program and a reconciliation of the Company's GAAP financial results to its non-GAAP financial results, please see the attached Press Release Exhibit.

For the year ending December 31, 2017, the Company is reaffirming its financial guidance as follows:

- Non-GAAP sales are estimated to be in the range of \$100 million to \$107 million

- Non-GAAP operating margin is estimated to be in the range of negative 70 percent to negative 65 percent, which includes:
 - Approximately \$11.0 million in non-cash, stock-based compensation expense
 - Approximately \$6.0 million to \$7.0 million of depreciation and amortization

Conference Call

The Company will hold a conference call and simultaneous webcast today at 4:30pm Eastern Time (1:30pm Pacific Time). The link to the webcast will be available by accessing the Investor Center of the Tandem Diabetes Care website at <http://investor.tandemdiabetes.com>, and will be archived for 30 days. To listen to the conference call via phone, please dial 855-427-4396 (U.S./Canada) or 484-756-4261 (International) and use the participant code "4168494".

Use of Non-GAAP Financial Measures

The Company presents certain non-GAAP financial measures in this press release, including historical and projected non-GAAP sales and operating margin, to provide information that may assist investors in understanding its financial results, assessing its prospects for future performance and allowing for a meaningful comparison of projected results to historical results. The Technology Upgrade Program discussed above has created and will continue to create unpredictable GAAP results for its duration. This is principally due to accounting complexities associated with the program that are dependent on a number of future events and variables that are difficult to estimate or predict. Due to these accounting complexities, and the resulting uncertainty, the Company is providing guidance for the year ending December 31, 2017 on a non-GAAP basis, which excludes the impact of the Technology Upgrade Program.

These non-GAAP financial measures will be used internally by the Company to analyze its operating performance and prospects for future performance for the duration of the Technology Upgrade Program. The principal limitation of these non-GAAP financial measures is that they do not necessarily reflect, and may not be a good estimate of, the amount that will actually be recorded in the Company's financial statements in accordance with GAAP. The non-GAAP financial information and guidance is not intended to be considered in isolation or as a substitute for, or superior to, financial information and guidance prepared and presented in accordance with GAAP. To the extent the Company utilizes such non-GAAP financial measures in the future, it expects to calculate them using a consistent method from period to period. Because of the difficulty in estimating the accounting impact from the Technology Upgrade Program, the Company cannot provide a reconciliation of non-GAAP financial guidance to GAAP financial guidance with any level of certainty and without unreasonable efforts. However, the Company has provided a reconciliation of its historical GAAP financial results to its historical non-GAAP financial results under the heading "Reconciliation of GAAP versus Non-GAAP Financial Results" in the attached Press Release Exhibit.

About Tandem Diabetes Care, Inc.

Tandem Diabetes Care, Inc. (www.tandemdiabetes.com) is a medical device company with an innovative, user-centric and integrated approach to the design, development and commercialization of products for people with diabetes who use insulin. The Company manufactures and sells the t:slim X2™ Insulin Pump, the slimmest and smallest durable insulin pump currently on the market, the t:flex® Insulin Pump, the first pump designed for people with greater insulin requirements, and the t:slim G4™ Insulin Pump, the first continuous glucose monitoring-enabled pump with touchscreen simplicity. Tandem is based in San Diego, California.

Follow Tandem Diabetes Care on Twitter @tandemdiabetes; use #t:slimX2, #t:slimG4, #t:flex, #t:connect, and \$TNDM.

Follow Tandem Diabetes Care on Facebook at www.facebook.com/TandemDiabetes.

Follow Tandem Diabetes Care on LinkedIn at <https://www.linkedin.com/company/tandemdiabetes>.

t:flex and Tandem Diabetes Care are registered trademarks, and t:slim X2 and t:slim G4 are trademarks of Tandem Diabetes Care, Inc.

Forward Looking Statement

This press release contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that concern matters that involve risks and uncertainties that could cause actual results to differ materially from those anticipated or projected in the forward-looking statements. These forward-looking statements include statements regarding, among other things, the impact of the implementation of the Technology Upgrade Program, the Company’s projected financial results, including its projected non-GAAP sales and non-GAAP operating margins, and the Company’s ability to execute its business plan and achieve its key goals for 2017. The Company’s actual results may differ materially from those indicated in these forward-looking statements due to numerous risks and uncertainties. For instance, the Company’s ability to achieve its goals for 2017 will be impacted by the Company’s ability to obtain regulatory approval for the t:slim X2 with Dexcom’s G5 integration and the timing of any such approvals; the Company’s ability to launch its new t:lock infusion set connector when anticipated; market acceptance of the Company’s new products and products under development by physicians and people with diabetes; the potential that newer products that compete with the Company’s products, or other technological breakthroughs for the monitoring, treatment or prevention of diabetes, may render the Company’s products obsolete or less desirable; and the potential that the process of purchasing the Company’s products, including insurance verification approval for individual customers, may delay or prevent the sale of the products. In addition, factors that will affect the Company’s financial results due to the Technology Upgrade Program are expected to include the mix of pumps sold; the percentage of customers that choose to upgrade their pump; the timing of the decision to upgrade their pump; and the upgrade option chosen by customers. Other risks and uncertainties include the Company’s inability to manufacture products in commercial quantities at an acceptable cost and in accordance with quality requirements; the Company’s inability to contract with additional third-party payors for reimbursement of the Company’s products; uncertainty associated with the development and approval of new products generally; possible future actions of the FDA or any other regulatory body or governmental authority; and other risks identified in the Company’s most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q, and other documents that the Company files with the Securities and Exchange Commission. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Tandem undertakes no obligation to update or review any forward-looking statement in this press release because of new information, future events or other factors.

TANDEM DIABETES CARE, INC.
GAAP CONDENSED BALANCE SHEETS
(in thousands)

	<u>March 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
	<u>(Unaudited)</u>	
Assets		
Current assets:		
Cash and cash equivalents and short-term investments	\$ 44,010	\$ 53,538
Restricted cash	-	2,000
Accounts receivable, net	7,687	11,172
Inventory, net	23,748	21,195
Other current assets	4,489	4,187
Total current assets	<u>79,934</u>	<u>92,092</u>
Restricted cash - long-term	10,000	-
Property and equipment, net	20,927	18,409
Other long term assets	1,853	1,891
Total assets	<u>\$ 112,714</u>	<u>\$ 112,392</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable, accrued expense and employee-related liabilities	\$ 19,004	\$ 19,325
Deferred revenue	3,746	5,208
Other current liabilities	6,465	6,943
Total current liabilities	<u>29,215</u>	<u>31,476</u>
Notes payable-long-term	73,763	78,960
Other long-term liabilities	11,604	7,883
Total liabilities	<u>114,582</u>	<u>118,319</u>
Total stockholders' equity	<u>(1,868)</u>	<u>(5,927)</u>
Total liabilities and stockholders' equity	<u>\$ 112,714</u>	<u>\$ 112,392</u>

TANDEM DIABETES CARE, INC.
GAAP CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(Unaudited)

	Three Months Ended March 31,	
	2017	2016
Sales	\$ 18,977	\$ 20,058
Cost of sales	12,224	13,130
Gross profit (loss)	6,753	6,928
Operating expenses:		
Selling, general and administrative	22,849	21,997
Research and development	5,130	4,169
Total operating expenses	27,979	26,166
Operating loss	(21,226)	(19,238)
Other income (expense), net:		
Interest and other income	59	118
Interest and other expense	(2,625)	(1,364)
Total other expense, net	(2,566)	(1,246)
Net loss	\$ (23,792)	\$ (20,484)
Net loss per share, basic and diluted	\$ (0.75)	\$ (0.68)
Weighted average shares used to compute basic and diluted net loss per share	31,889	30,294



Press Release Exhibit

Summary of Technology Upgrade Program and Associated Reconciliation of GAAP versus Non-GAAP Financial Results

Program Overview

In July 2016, Tandem Diabetes Care, Inc. (“Tandem” or the “Company”) launched a Technology Upgrade Program (the “Upgrade Program”) as a pathway for its t:slim® and t:slim G4™ Insulin Pump customers to experience the Company’s latest technology, the t:slim X2™ Insulin Pump platform, under a variable pricing structure. The Company began shipping the t:slim X2 Insulin Pump in October 2016 and is no longer offering the t:slim® Insulin Pump to new customers.

The t:slim X2 Insulin Pump features new hardware advancements, including a two-way Bluetooth® wireless technology radio for communicating with more than one external device at a time. The Company expects these advancements, together with the Company’s future anticipated use of the Tandem Device Updater to deliver remote software updates for the t:slim X2, will offer customers a path to new innovations separate from the typical 4-year insurance pump replacement cycle. The Upgrade Program is available to eligible customers through September 30, 2017.

Accounting Treatment Overview

Pursuant to applicable GAAP revenue recognition standards, revenue is recognized when the product is delivered or when an obligation is fulfilled, among other requirements. Under the Upgrade Program, eligible customers will be provided the opportunity to receive a t:slim X2 Insulin Pump at a future date. This creates potential future obligations for the Company that prevent the full recognition of revenue and cost of sales at the time of the customer’s initial purchase of an insulin pump, which results in a deferral of revenue and cost of sales on the Company’s financial statements. The deferrals will generally be recognized at the earlier of when the obligation for such upgrades and services are fulfilled or when the Upgrade Program expires. Any fees received by the Company under the Upgrade Program and the Company’s cost of fulfilling the associated obligation will also be recognized at that time.

Reconciliation of GAAP versus Non-GAAP Financial Results

Due to this high degree of accounting complexity, which is dependent on a number of future events and variables that are difficult to estimate or predict, the Upgrade Program creates unpredictable GAAP results for the duration of the Program. To aid investors in better understanding the Company’s performance and minimize potential confusion when comparing its current and future results to historical results, the Company has provided non-GAAP financial information in the accompanying press release, in addition to providing GAAP financial information. In the following tables, the Company has provided a reconciliation of its GAAP financial results to its non-GAAP financial results, which illustrates the impact of the Upgrade Program:

For the three months ended March 31, 2017, the impact of the Upgrade Program was as follows:

Impact of Technology Upgrade Program (1)

(in millions)	GAAP Financial Results	Deferrals at Initial Sale ¹	Recognition of Deferrals ²	Upgrade Fulfillments ³
Sales	\$ 19.0	\$ 0.1	\$ (1.5)	\$ (0.1)
Cost of sales	\$ 12.2	\$ —	\$ (0.4)	\$ (0.4)
Gross profit (loss)	\$ 6.8	\$ 0.1	\$ (1.1)	\$ 0.3
Gross margin %	36%			
Operating loss	\$ (21.2)	\$ 0.1	\$ (1.1)	\$ 0.3
Operating margin %	(112)%			

(1) Table may not foot due to rounding

Since the launch of t:slim X2 pump in the fourth quarter of 2016, the Company has fulfilled approximately 2,000 upgrades under the Technology Upgrade Program, and recorded an incremental \$1.1 million cost of sales, net of upgrade fees. As of March 31, 2017, the Company recorded \$3.0 million in deferred revenue and \$0.4 million in deferred cost of sales, which will be recognized at the earlier of when the upgrade obligations are fulfilled or when the program expires on September 30, 2017.

Non-GAAP Accounting Definitions

1) Deferrals at Initial Sale - The deferral of initial sales and cost of sales for eligible pump shipments are summarized in the following table:

Deferral Treatment for Eligible Shipments on or After July 1, 2016

Product	Sales Deferral	Cost of Sales Deferral
t:slim Insulin Pump	100% of each sale as a right of return.	100% of the manufacturing cost as a right of return.
t:slim G4 Insulin Pump	A portion of each sale as a guarantee liability.	No deferral.

2) Recognition of Deferrals – This reflects any changes in subsequent periods for deferrals made at the time of the initial sale (see Deferrals at Initial Sale above). It includes recognition of amounts previously deferred when actual product upgrades occur. It will eventually also include a reversal of any remaining deferrals when the program expires for customers who did not elect the upgrade or service options.

3) Upgrade Fulfillments – This reflects incremental revenue recognized from an upgrade or service fee, if any, and the cost of sales associated with completing that upgrade or service. Approximately 2,000 upgrade fulfillments have occurred since the fourth quarter of 2016, when the t:slim X2 Insulin Pump became available. At that time, the Company commenced reporting Recognition of Deferrals and Upgrade Fulfillments.

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