# 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): January 9, 2015

# **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)

k 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 sions:
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))

#### Item 8.01 Other Events.

On January 12, 2015, Tandem Diabetes Care, Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) has granted the company clearance to market the t:flex™ Insulin Pump. The press release announcing the FDA clearance is attached hereto as Exhibit 99.1 and 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 it 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.

#### Number Description

99.1 Press release of Tandem Diabetes Care, Inc. dated January 12, 2015.

# 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.

Tandem Diabetes Care, Inc.

Date: January 12, 2015

/s/ David B. Berger

David B. Berger General Counsel

# INDEX TO EXHIBITS

# Number Description

99.1 Press release of Tandem Diabetes Care, Inc. dated January 12, 2015.



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#### FOR IMMEDIATE RELEASE

#### Tandem Diabetes Care Announces FDA Clearance of the t:flex™ Insulin Pump

Largest-capacity Insulin Pump Cleared for People with Greater Insulin Needs

**San Diego, January 12, 2015** – Tandem Diabetes Care<sup>®</sup>, Inc. (NASDAQ: TNDM), a medical device company and manufacturer of the t:slim<sup>®</sup> Insulin Pump, today announced that the U.S. Food and Drug Administration (FDA) has granted the Company clearance to market the t:flex<sup>™</sup> Insulin Pump. At 480 units, the insulin reservoir of the t:flex Pump has the largest capacity currently available in the United States.

"In recognizing that one size does not fit all, the t:flex Pump was developed using Tandem's proprietary technology platform to bring t:slim's benefits to people with greater insulin needs," said Kim Blickenstaff, President and Chief Executive Officer of Tandem Diabetes Care. "This first expansion of our product portfolio reflects our ongoing commitment to deliver user-friendly products that address unmet needs in the diabetes community."

People with diabetes require different amounts of insulin based on their level of insulin sensitivity, which can vary significantly from person to person. The t:flex Pump is designed for people who require more than 100 units of U-100 insulin per day, such as teenagers with type 1 diabetes and many people with type 2 diabetes. The pump offers people with greater insulin needs the benefits of pump therapy without the frequent reservoir changes required by 200- and 300-unit capacity pumps. It incorporates the same slim design, advanced Micro-Delivery<sup>TM</sup> technology, and simple-to-use, touch-screen interface as the t:slim Insulin Pump, which is rated #1 by pump users.<sup>1</sup>

The t:flex Pump is expected to launch in the United States in the second quarter of 2015. People interested in more information about the t:flex Pump can visit the Company website at www.tandemdiabetes.com/tflex. The Company will report its fourth quarter and year-end 2014 financial results later in the first quarter, and anticipates providing guidance for 2015, including initial commercialization objectives for the t:flex Pump, at that time.

#### **Insulin Pump Use and Diabetes**

Diabetes is a chronic, life-threatening disease that affects more than 29 million people in the United States, or nearly 1 in 10 Americans. Tandem estimates that 3 million people in the United States require daily administration of insulin and are candidates for pump therapy. More than 400,000 Americans with type 1 diabetes use an insulin pump, or approximately 27% of the type 1 diabetes population. In addition, approximately 75,000 Americans with type 2 diabetes use an insulin pump, a small fraction of the type 2 diabetes population.

Recent studies suggest that insulin pump therapy reduces average blood glucose levels and overall insulin needs in people with type 2 diabetes compared with standard therapy using multiple daily injections.<sup>2</sup> In Tandem's market research, two-thirds of endocrinologists cited limited capacity as the number one barrier to insulin pump adoption for people with type 2 diabetes who are insulin dependent.

- 1 dQ&A Patient Panel, Q2 2014
- 2 Aronson Ronnie, Cohen Ohad, Conget Ignacio, Runzis Sarah, Castaneda Javier, de Portu Simona, Lee Scott, Reznik Yves, and for the OpT2mise Study Group. Diabetes Technology & Therapeutics. July 2014, 16(7): 414-420. doi:10.1089/dia.2013.0363.

#### About Tandem Diabetes Care, Inc.

Tandem Diabetes Care, Inc. (<a href="www.tandemdiabetes.com">www.tandemdiabetes.com</a>) 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® Insulin Pump, the slimmest and smallest durable insulin pump currently on the market, and the t:flex<sup>TM</sup> Insulin Pump, the first pump designed for people with greater insulin requirements. Tandem is based in San Diego, California.

#### **Forward Looking Statement**

This press release includes forward-looking statements relating to the anticipated timing of the commercial launch of the t:flex Pump and the potential advantages of the t:flex Pump over existing insulin pumps. Such statements are based on management's current expectations, but actual results may differ materially due to various risks and uncertainties, including: Tandem's ability to begin commercial scale manufacturing of the t:flex Pump and associated cartridges; the potential that newer products that compete with the t:flex Pump, or other technological breakthroughs for the monitoring, treatment or prevention of diabetes, may render the t:flex Pump obsolete or less desirable; and other risks identified in Tandem's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q. 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 any forward-looking statement in this press release.

The t:flex Insulin Pump is indicated for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater.

Follow Tandem Diabetes Care on Twitter @tandemdiabetes, use #tslim, #tflex, #tconnect, 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:slim, and Tandem Diabetes Care are registered trademarks, and t:flex is a trademark of Tandem Diabetes Care, Inc.