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): September 8, 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)

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))

Item 8.01 Other Events

On September 9, 2015, we issued a press release announcing that the U.S. Food and Drug Administration (FDA) approval of the t:slim G4[™] Insulin Pump. The press release announcing the FDA approval 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.

99.1 Press release of Tandem Diabetes Care, Inc. dated September 9, 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.

/s/ David B. Berger

David B. Berger General Counsel and Secretary

Date: September 9, 2015

INDEX TO EXHIBITS

<u>Number</u> <u>Description</u>

99.1 Press release of Tandem Diabetes Care, Inc. dated September 9, 2015.



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Investor Contact: Susan Morrison 858-366-6900 x7005 smorrison@tandemdiabetes.com

FOR IMMEDIATE RELEASE

Tandem Diabetes Care Announces FDA Approval of t:slim G4 Insulin Pump with CGM Integration

The First and Only CGM-enabled Touch-Screen Pump

San Diego, September 9, 2015 – Tandem Diabetes Care®, Inc. (NASDAQ: TNDM) today announced U.S. Food and Drug Administration approval of the t:slim $G4^{TM}$ Insulin Pump, the first and only touch-screen pump with continuous glucose monitoring (CGM) integration, for use by people 12 years of age or older who use insulin. It combines features of the t:slim® Insulin Pump and Dexcom G4® PLATINUM CGM System, devices that have consistently ranked #1 in independent surveys¹, into a single device that is simple to use. The t:slim G4 Pump is the only pump that conveniently displays CGM graphs and trend information with current insulin delivery activity together on the home screen to help make informed treatment decisions. Orders for the t:slim G4 Insulin Pump can be placed now with shipments expected to begin in October 2015.

"The t:slim G4 Pump combines our intuitive touch-screen interface and bright color display with Dexcom's CGM technology, giving the diabetes community a powerful new tool to help simplify therapy management," said Kim Blickenstaff, President and Chief Executive Officer of Tandem Diabetes Care. "CGM integration has been one of the most requested features since the launch of the t:slim Pump. The addition of t:slim G4 to our product family allows us to address a wider variety of diabetes management needs through the broadest range of insulin pump options available from one company."

"The integration of Tandem's touch-screen interface and Dexcom's G4 PLATINUM CGM product could prove to be a powerful combination for people with diabetes," said Kupper Wintergerst, MD, pediatric endocrinologist at the University of Louisville and director of the Wendy L. Novak Diabetes Care Center in Louisville, KY. "It's great to have another integrated option for my patients, particularly one with an age indication for people as young as 12 years old."

"We believe the t:slim G4 Pump's touch screen technology and simple user interface are a great combination for Dexcom G4 PLATINUM CGM integration," said Steve Pacelli, EVP, Strategy and Corporate Development at Dexcom. "CGM-integration is key to future automated insulin delivery technology, and we are pleased to be working with a company like Tandem who is continuously innovating to make diabetes technology simpler to use for people with diabetes."

¹ dQ&A USA Diabetes Connections Surveys. t:slim Pump: 2013-2014. Dexcom G4 PLATINUM CGM: 2009-2014.

The t:slim G4 Pump is the newest addition to the Company's family of products, which includes the t:slim® and t:flex[™] Insulin Pumps. Each pump in the portfolio features a touch-screen with a streamlined, user-friendly interface. This provides people rapid access to frequently used features while eliminating the need for excessive scrolling and button pressing, making these features simple to learn and simple to use. Each Tandem product utilizes modern technology, such as a built-in rechargeable battery and micro-USB port for convenient charging and fast data transfers. They also feature the Company's Micro-Delivery® technology that allows for basal delivery every 5 minutes in increments as small as 0.001 unit. The t:slim G4 and t:slim Pumps are the slimmest and smallest durable insulin pumps on the market, yet still hold up to 300 units of insulin, and the t:flex offers similar size benefits while holding up to 480 units of insulin.

The t:slim G4 Pump can operate as a stand-alone insulin pump without CGM, or be paired with a Dexcom G4 PLATINUM sensor. When paired with a sensor, the CGM component of the pump closely mimics the interface of the Dexcom system, tracking glucose continuously and displaying color-coded graphs and arrows directly on the Pump's home screen². The system also allows users to program personalized information, such as glucose targets and alerts, and has an alarm feature to notify the user if glucose levels rise or fall to dangerous levels.

For additional product and safety information, or to begin the order process, visit www.tandemdiabetes.com/tslimG4 or call (877) 801-6901, Monday – Friday between 6am and 5pm Pacific Time

Download Tandem's free t:simulator[™] App to experience the t:slim G4 Pump's touch screen interface directly on your mobile device. For more information and to download the app, visit http://www.tandemdiabetes.com/tsimulator.

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 more than 3 million people in the United States require daily administration of insulin and are candidates for pump therapy. More than 425,000 Americans with type 1 diabetes use an insulin pump, or approximately 27% of the type 1 diabetes population. In addition, approximately 125,000 Americans with type 2 diabetes use an insulin pump, a small fraction of the type 2 diabetes population.

Conference Call Details:

The Company will hold a conference call and simultaneous webcast on September 9, 2015 at 4:30pm Eastern Time (1:30pm Pacific Time) to discuss FDA approval of the t:slim G4 Insulin Pump with CGM Integration. To listen to the conference call, please dial (855) 427-4396 (US/Canada) or (484) 756-4261 (International) and use the participant code "37158883". A link to the webcast will be available on Tandem Diabetes Care's Investor Center website located at http://investor.tandemdiabetes.com in the "Investor Events" section. An archive of the webcast will be available for 30 days following the event.

About Tandem Diabetes Care, Inc.

Tandem Diabetes Care, Inc. (<u>www.tandemdiabetes.com</u>) 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, the t:flexTM Insulin Pump, the first pump designed for people with greater insulin requirements, and the t:slim $G4^{TM}$ Insulin Pump, the first CGM-enabled pump with touch-screen simplicity. Tandem is based in San Diego, California.

² A minimum of two finger sticks a day is required for calibration. System may require more.

Forward Looking Statement

This press release includes forward-looking statements relating to the anticipated timing of the commercial launch of the t:slim G4 Pump, the anticipated benefits associated with use of the t:slim G4 Pump and the potential advantages of the t:slim G4 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:slim G4 Pump and associated cartridges; the potential that newer products that compete with the t:slim G4 Pump, or other technological breakthroughs for the monitoring, treatment or prevention of diabetes, including potential new products offered by Dexcom, may render the t:slim G4 Pump obsolete or less desirable; the potential that customers may not perceive the anticipated benefits associated with the use of the t:slim G4 Pump; 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.

Follow Tandem Diabetes Care on Twitter @tandemdiabetes, use #tslim, #tslimG4, #tflex, #tconnect, and \$TNDM. Follow Tandem Diabetes Care on Facebook at <u>www.facebook.com/TandemDiabetes</u>. Follow Tandem Diabetes Care on LinkedIn at <u>https://www.linkedin.com/company/TandemDiabetes</u>

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