

TANDEM DIABETES CARE INC

FORM 8-K (Current report filing)

Filed 08/28/17 for the Period Ending 08/25/17

Address	11045 ROSELLE STREET SUITE 200 San Diego, CA 92121
Telephone	858-366-6900
CIK	0001438133
Symbol	TNDM
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): August 25, 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 8.01 Other Events

On August 25, 2017, the U.S. Food and Drug Administration (FDA) approved our pre-market application (PMA) for the t:slim X2 Insulin Pump with Dexcom G5[®] Mobile continuous glucose monitoring (CGM) integration. The software featured on this newly approved pump will also be offered to current t:slim X2 Pump users at no cost via remote software update, allowing them to add CGM integration to their existing t:slim X2 Pumps from home using a personal computer. The t:slim X2 Pump with Dexcom G5 Mobile CGM integration is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin for individuals 6 years of age and greater.

On August 28, 2017 we issued a press release announcing the FDA approval and commercial launch of the t:slim X2 Insulin Pump with Dexcom G5 Mobile integration. The accompanying press release 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.

<u>Number</u>	<u>Description</u>
99.1	Press release of Tandem Diabetes Care, Inc. dated August 28, 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.

Tandem Diabetes Care, Inc.

Date: August 28, 2017

/s/ David B. Berger

David B. Berger

Executive Vice President, General Counsel and Secretary

INDEX TO EXHIBITS

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FOR IMMEDIATE RELEASE**Tandem Diabetes Care Announces FDA Approval and Launch of t:slim X2 Insulin Pump with Dexcom G5 Mobile CGM Integration**

– Software Update Available for Current t:slim X2 Pump Users Via Personal Computer –

San Diego, August 28, 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 announced U.S. Food and Drug Administration (FDA) approval and commercial launch of the t:slim X2™ Insulin Pump with Dexcom G5® Mobile continuous glucose monitoring (CGM) integration, the first sensor-augmented insulin pump approved to let users make treatment decisions without pricking their finger ¹. The software featured on this pump will also be available to current t:slim X2 Pump users at no cost via remote software update, allowing them to add CGM integration to their existing pumps from home using a personal computer. Individual emails are being sent directly to t:slim X2 Pump customers with instructions on how to perform the update. The t:slim X2 Pump with Dexcom G5 Mobile CGM integration is approved for ages 6 and older. This approval marks the Company's fifth new insulin pump launch in only 5 years and the second featuring Dexcom technology. It is the only available pump that conveniently displays a user's insulin delivery activity and Dexcom G5 Mobile CGM data together on a single device. The t:slim X2 Pump is also the only insulin pump capable of remote software updates ², allowing existing users to add features like CGM integration from home. It is up to 38% smaller than other pumps ³, but includes advanced features like a large color touchscreen, Bluetooth® radio, rechargeable battery, USB connectivity, 300-unit insulin capacity and watertight construction (IPX7) ⁴.

"We are setting a new standard in our industry by simultaneously offering our existing and future customers the benefits of best-in-class CGM integration on our simple-to-use touchscreen insulin pump," said Kim Blickenstaff, president and CEO of Tandem Diabetes Care. "The t:slim X2 Pump is designed to accelerate the pace in which we can bring new innovations to people with diabetes, which is of particular importance as we develop software updates to add automated insulin delivery algorithms to our platform."

"Dexcom has been moving its technology forward at a rapid pace, and Tandem's ability to roll out remote software updates like this opens up exciting possibilities for faster integrations of our future products," said Steve Pacelli, Executive Vice President of Strategy and Corporate Development at Dexcom. "We are excited to have our latest CGM technology integrated with their t:slim X2 Insulin Pump, and to see it offered not only to new customers but also to existing t:slim X2 Pump users."

The t:slim X2 Pump can operate as a stand-alone insulin pump without CGM, or be paired with the Dexcom G5 Mobile CGM to track glucose continuously and display that information directly on the pump's home screen. Dexcom G5 Mobile is the only CGM system FDA-approved to let users make treatment decisions without pricking their finger. Dexcom is also consistently rated the #1 CGM brand in independent patient surveys⁵. In addition to integration with the t:slim X2 Pump, dynamic glucose data from the Dexcom G5 Mobile CGM can be easily accessed and shared using a compatible mobile device.

For additional t:slim X2 Pump product and safety information, or to begin the order process, visit www.tandemdiabetes.com/tslimX2 or call (877) 801-6901, Monday – Friday between 6am and 5pm Pacific Time

Download Tandem's free t:simulator™ App to experience the touchscreen interface of the t:slim X2 Pump with Dexcom G5 Mobile CGM integration directly on your mobile device. For more information and to download the app, visit <http://www.tandemdiabetes.com/tsimulator>.

Information for Current t:slim X2 Pump Users

All eligible t:slim X2 Pump users have the option to add Dexcom G5 Mobile CGM integration via a software update using a personal computer. Individual emails are being sent directly to t:slim X2 Pump customers with instructions on how to perform the update. The software update is Mac® and PC compatible. For more information on system requirements, visit www.tandemdiabetes.com/updater.

Remote Software Updates for Insulin Pumps

Tandem is the only company with a tool for providing remote software updates for its insulin pumps using a personal computer. The power of the t:slim X2 Pump's touchscreen allows for buttons to be moved and data like the interactive CGM screen to be added via software updates without getting a new device. With innovations in diabetes technology consistently moving faster than the typical insurance pump replacement cycle, remote software updates make it easier to make a purchasing decision today without worrying that the device will soon be outdated. Future Tandem products are being developed with software updates in mind, with the goal of delivering new technologies to both new and current customers at the same time.²

The Benefits of Insulin Pump Therapy with CGM

Published studies have shown that insulin pump therapy, when paired with proper training and support, can result in better blood sugar control and lower total daily insulin use compared to multiple daily injections.^{6, 7, 8} CGM has demonstrated improved blood sugar control, increased confidence related to the risk of low blood sugar, and decreased diabetes stress.^{9, 10} Combining insulin pump therapy and CGM has demonstrated the best overall glucose control compared to multiple daily injections or pump therapy alone, in addition to the quality of life improvements associated with each individual therapy.⁹

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.

The t:slim X2 Pump with Dexcom G5 Mobile CGM integration will replace the Company's previous-generation t:slim G4™ Pump. The Company will continue to service all current t:slim G4 Pumps for the duration of their warranty. An upgrade program is available through September 30, 2017 for t:slim and t:slim G4 Pump users interested in accessing the t:slim X2 Pump. For more information, visit www.tandemdiabetes.com/upgrade.

About Tandem Diabetes Care, Inc.

Tandem Diabetes Care, Inc. (www.tandemdiabetes.com) is a medical device company dedicated to improving the lives of people with diabetes through relentless innovation and revolutionary customer experience. The Company takes an innovative, user-centric approach to the design, development and commercialization of products for people with diabetes who use insulin. Tandem manufactures and sells the t:slim X2™ Insulin Pump, the only pump capable of remote feature updates using a personal computer, and the t:flex® Insulin Pump, the first pump designed for people with greater insulin requirements. Tandem is based in San Diego, California.

Follow Tandem Diabetes Care on Twitter @tandemdiabetes; use #tslimX2, #tslimG4, #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>.

Tandem Diabetes Care is a registered trademarks, and t:slim X2 and t:slim G4 are trademarks of Tandem Diabetes Care, Inc. Dexcom and Dexcom G5 are registered trademarks of Dexcom, Inc. Bluetooth® is a registered trademark of Bluetooth SIG, Inc. All other trademarks are the property of their respective owners.

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 the Company’s ability to develop software updates that add automated insulin delivery algorithms to the t:slim X2 and the potential for faster integration with Dexcom products in the future. The Company’s actual results may differ materially from those indicated in these forward-looking statements due to numerous risks and uncertainties, including the Company’s ability to complete the development of automated insulin delivery algorithms for the t:slim X2, the Company’s ability to successfully complete clinical trials for new products when anticipated (or at all), the potential that the results of any such clinical trials may not be sufficient to support regulatory approvals for new products as anticipated and the Company’s ability to obtain regulatory approvals for future products and product features generally. Other risks and uncertainties are identified in the Company’s most recent Annual Report on Form 10-K and 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.

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- ¹ CGM-based treatment requires fingersticks for calibration; may result in hypoglycemia if calibration not performed, when taking acetaminophen, or if symptoms/expectations do not match CGM readings.
 - ² Additional feature updates are not currently available for the t:slim X2 Pump with Dexcom G5 Mobile CGM integration and are subject to future FDA approvals. Charges may apply.
 - ³ 38% smaller than MiniMed 630G and 670G and at least 28% smaller than MiniMed 530G, Animas Vibe and Omnipod System. Data on file, Tandem Diabetes Care.
 - ⁴ Tested to 3 feet for 30 minutes (IPX7 rating).
 - ⁵ dQ&A USA Diabetes Connections Surveys, 2009-2016.
 - ⁶ Reznik Y, Cohen O, Aronson R, et al. *Lancet*. 2014;384(9950):1265-1272.
 - ⁷ Hoogma RPLM, Hammond PJ, Gomis R, et al. *Diabet Med*. 2005;23:141-147.
 - ⁸ Bode BW, Sabbah HT, Gross TM. *Diabet Metab Res Rev*. 2002;18(suppl 1):S14-S20.
 - ⁹ Foster N, Miller K, Tamborlane W, Bergenstal R, Beck R, & T1D Exchange Clinical Network (2016). *Diabetes Care* 2016 Jun; 39(6): e81-e82.
 - ¹⁰ Polonsky B, Hessler D, Ruedy K, Beck R. & DIAMOND Study Group. *Diabetes Care*. 2017. doi:10.2337/dc17-0133. [Epub ahead of print]