

**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): February 16, 2022

Tandem Diabetes Care, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)
11075 Roselle Street
San Diego California
(Address of principal executive offices)

001-36189
(Commission
File Number)

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

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

<u>Title of Each Class</u>	<u>Trading Symbol</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock, par value \$0.001 per share	TNDM	NASDAQ Global Market

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 February 15, 2022, the U.S. Food and Drug Administration (FDA) cleared our 510(k) application for the t:slim X2 insulin pump to bolus insulin using the t:connect mobile app.

On February 16, 2022, we issued a press release announcing the foregoing FDA clearance and also referring to the planned future commercial launch of related updates to our t:slim X2 insulin pump and t:connect mobile app. 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 February 16, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 Tandem Diabetes Care, Inc.

By: /s/ LEIGH A. VOSSELLER
 Leigh A. Vosseller
 Executive Vice President, Chief
 Financial Officer and Treasurer

undersigned hereunto duly authorized.

Date: February 16, 2022

**Media Contact:**

Steve Sabicer
714-907-6264
ssabicer@thesabicergroup.com

Investor Contact:

Susan Morrison
858-366-6900
IR@tandemdiabetes.com

FOR IMMEDIATE RELEASE**Tandem Diabetes Care Announces FDA Clearance for the t:slim X2 Insulin Pump to Bolus Using the t:connect Mobile App**

First Smartphone App FDA cleared for Insulin Delivery on Both iOS and Android Operating Systems

San Diego, February 16, 2022 - Tandem Diabetes Care, Inc. (NASDAQ:TNDM), a leading insulin delivery and diabetes technology company, today announced U.S. Food and Drug Administration (FDA) clearance of bolus insulin dosing on the t:slim X2 insulin pump using the t:connect mobile app. This represents the first-ever FDA-cleared smartphone application capable of initiating insulin delivery on both iOS and Android operating systems. The updated t:connect mobile app is designed to offer t:slim X2 insulin pump users the ability to program and cancel bolus insulin requests through the convenience of their compatible smartphone.

“This FDA clearance further validates our commitment to innovation and the diabetes community by providing one of the most requested feature enhancements,” said John Sheridan, president and CEO of Tandem Diabetes Care. “With the improvements in diabetes management provided by Tandem’s Control-IQ technology, giving a meal bolus is now the most common reason a person interacts with their pump, and the ability to do so using a smartphone app offers a convenient and discrete solution.”

When released, this new feature will be offered in the United States for no additional cost to new t:slim X2 insulin pump customers and to in-warranty customers through a remote software update for the t:slim X2 insulin pump and the updated t:connect mobile app. The Company intends to roll out the mobile bolus feature update throughout the spring in a series of limited launch groups, followed by an expanded launch later this summer. Limited launch participants have already been selected.

The t:connect mobile app is a secure, user-friendly mobile application that, when paired with a t:slim X2 insulin pump, discreetly displays the user’s pump information on their personal smartphone. In addition to the newly cleared bolus feature, the mobile app displays the last 24 hours of glucose trends, pump status changes, and insulin therapy data, including basal and bolus deliveries and suspensions of insulin delivery. The app also displays pump alerts and alarms, and it securely uploads data into the cloud-based t:connect web application wirelessly. Importantly, the t:slim X2 insulin pump functions independently from the t:connect mobile app, therefore a user always retains the freedom to view pump therapy data, program requests and cancel bolus insulin requests from their pump.

The t:connect mobile app is compatible with select versions of both iOS and Android operating systems in the United States. To ensure compatibility, Tandem verifies each combination of device and operating system works as intended to program and cancel a bolus from your smartphone. This means that not every smartphone will be able to use the bolus feature within the t:connect mobile app. More information is available at www.tandemdiabetes.com.

In addition to the t:connect mobile app being the first to receive FDA clearance on both iOS and Android operating systems to deliver insulin from a personal smartphone, Tandem was also the first to receive an interoperable automated glycemic controller designation with Control-IQ technology in December 2019, the first to receive an alternate controller-enabled infusion pump classification in February 2019, and the first insulin pump designated as compatible with integrated continuous glucose monitoring devices in June 2018.

Forward-Looking Statements:

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. These forward-looking statements relate to, among other things, the anticipated timing for availability of the new features in the t:connect mobile app, the compatibility of the mobile app with smartphone hardware and operating systems and our ability to offer the related pump software update for current t:slim X2 pump users. These forward-looking statements are subject to numerous risks and uncertainties, including risks associated with the research and development process generally, such as the completion of final testing and validation of products and related systems in compliance with applicable quality system requirements, our ability to operate and maintain a system to facilitate online training and prescription handling for existing t:slim X2 pump customers upgrading their existing devices, and the risk that we may encounter other challenges that may delay the commercial launch of new features, as well as other risks identified in our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, and other documents that we file with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Actual results could differ materially from those anticipated or projected in the forward-looking statements. 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.

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’s flagship product, the t:slim X2 insulin pump, is capable of remote software updates using a personal computer, and features integrated continuous glucose monitoring. Tandem is based in San Diego, California. Tandem Diabetes Care, Control-IQ, and t:connect are trademarks registered in the U.S. and/or other countries and t:slim X2 is a trademark of Tandem Diabetes Care, Inc.

Visit www.tandemdiabetes.com/mobile-bolus for important safety information.

Follow Tandem Diabetes Care on Twitter @tandemdiabetes; use #tslimX2, 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 Contact:

Susan Morrison
858-366-6900
IR@tandemdiabetes.com