TANDEM DIABETES CARE INC
Form 8-K
June 22, 2018

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): June 21, 2018

Tandem Diabetes Care, Inc.

(Exact name of registrant as specified in its charter)

| Delaware | 001-36189 | 20-4327508 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (I.R.S. Employer Identification No.) |

| 11075 Roselle Street, San Diego, CA | 92121 |
|---|---|
| (Address of principal executive offices) | (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 June 21, 2018, the U.S. Food and Drug Administration (FDA) approved our pre-market application (PMA) for the t:slim X2™ Insulin Pump with Basal-IQ™ technology, a predictive low glucose suspend (PLGS) feature designed to help reduce the frequency and duration of low glucose events (hypoglycemia). The t:slim X2 with Basal-IQ technology is also the first insulin pump designated as compatible with integrated continuous glucose monitoring (iCGM) devices, such as the Dexcom G6 continuous glucose monitoring (CGM) system. The software featured on this newly approved pump will be offered to current in-warranty t:slim X2 Pump users in the United States free of charge via remote software update. The t:slim X2 Pump with Basal-IQ technology 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 June 21, 2018 we issued a press release announcing the FDA approval and planned commercial launch of the t:slim X2 Insulin Pump with Basal-IQ technology and related software updates for eligible t:slim X2 users. 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.

| Number | Description |
|---|---|
| 99.1 | Press release of Tandem Diabetes Care, Inc. dated June 21, 2018. |

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: June 21, 2018 /s/ David B. Berger
David B. Berger
Executive Vice President, General Counsel and Secretary