# 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 16, 2020**

---

# 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** | | **92121** |
| **San Diego California** | | **(Zip Code)** |
| **(Address of principal executive offices)** | | |

**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:**

| Title of Each Class | Symbol | Name of Exchange on Which Registered |
|---|---|---|
| **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 June 16, 2020, the U.S. Food and Drug Administration (FDA) cleared an expanded pediatric indication for our t:slim X2™ insulin pump with Control-IQ™ technology to children age six and older. The product was previously approved for ages 14 and older.

On June 17, 2020 we issued a press release announcing FDA clearance of an expanded pediatric indication of the t:slim X2 insulin pump with Control-IQ technology. 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 17, 2020. |

**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.

By: /s/ David B. Berger

David B. Berger

Executive Vice President, Chief Legal & Compliance Officer

Date: June 17, 2020

**FOR IMMEDIATE RELEASE**

**Tandem Diabetes Care Announces Expanded Pediatric Indication of the t:slim X2 Insulin Pump with Control-IQ Advanced Hybrid Closed-Loop Technology**

**San Diego, CA – June 17, 2020** – 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 an expanded pediatric indication for the t:slim X2™ insulin pump with Control-IQ™ technology to children age six and older. The product was previously approved for ages 14 and older. Control-IQ technology is an advanced hybrid closed-loop feature designed to increase time in range (70-180 mg/dL).[1]

Control-IQ technology helps simplify diabetes management for younger patients by adjusting insulin delivery to help prevent highs and lows, automatically delivering correction boluses up to once per hour, and offering exercise and sleep-specific features. Integrated with Dexcom G6 continuous glucose monitoring (CGM), Control-IQ technology requires no fingersticks for calibration or diabetes treatment decisions.[2]

In a recent six-month study of children age 6 to 13 using the t:slim X2 pump with Control-IQ technology, sensor time in range (TIR) increased to 67 percent from 53 percent compared to those in the control group using sensor-augmented pump (SAP) alone ($p<0.001$). Overnight, children using Control-IQ technology in the same study stayed in range an average of 80 percent of the time, compared to 54 percent in the control group. This data from the *International Diabetes Closed Loop Protocol-5* (DCLP5) study, funded by the National Institutes of Health (NIH), was presented earlier this year at the 13th International Conference on Advanced Technologies and Treatments for Diabetes (ATTD) in Madrid, Spain.[3]

“Nearly 40,000 t:slim X2 users have updated their pump with our revolutionary Control-IQ technology,” said John Sheridan, president and CEO of Tandem Diabetes Care. “The overwhelmingly positive benefits that people report experiencing can now be offered to a broader group of children with diabetes, which is particularly important as younger people often struggle with their glucose control.”

**Benefits of Control-IQ Advanced Hybrid Closed-Loop Technology:**

**Predicts and helps prevent lows and highs** – Control-IQ technology uses CGM readings to predict glucose values 30 minutes ahead. If glucose values are predicted to drop below 112.5 mg/dL, basal insulin delivery is reduced, and when predicted to be below 70 mg/dL, basal insulin delivery is stopped. If glucose values are predicted to be above 160 mg/dL in the next 30 minutes, basal insulin will be increased to help keep glucose in range (70-180 mg/dL).[1]

**Automatic Correction Boluses** – If glucose values are predicted to be above 180 mg/dL, Control-IQ technology calculates a correction bolus with a target of 110 mg/dL and delivers 60 percent of that value. It will do this up to once an hour as needed.[4]

**Accommodates for sleep and exercise** – Control-IQ technology offers optional settings for sleep and exercise that change the treatment values to better match the different physiologic needs during these activities.

**No fingersticks** – With Dexcom G6 CGM integration, the Control-IQ feature works with no fingersticks required for mealtime dosing or calibration.[2] Other benefits of the Dexcom G6 CGM include an extended 10-day wear, acetaminophen blocking,[5] and the ability to share real-time CGM data with up to 10 followers.[6]

**Standard Features of the t:slim X2 Insulin Pump:**

**Color touchscreen** – The large color touchscreen on the t:slim X2 pump is easy to read, simple to learn, and intuitive to use for anyone familiar with a smartphone or tablet.

**Small and discreet** – The t:slim X2 pump is up to 38 percent smaller than other pumps,[7] yet can hold up to 300-units of insulin.

**Can be used with or without the Control-IQ feature or CGM** – When advanced features are turned off, the t:slim X2 pump removes the CGM chart from the screen and puts the Bolus and Option buttons front and center for easy access.

**For additional product and safety information, or to begin the order process, visit http://tandemdiabetes.com/controliq**

**Important Safety Information for the t:slim X2 insulin pump with Control-IQ technology**

Caution: RX ONLY. The t:slim X2 pump and Control-IQ technology are intended for single patient use. The t:slim X2 pump and Control-IQ technology are indicated for use with NovoLog or Humalog U-100 insulin. t:slim X2 insulin pump: The t:slim X2 insulin pump with interoperable technology is an alternate controller enabled (ACE) pump that is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in people requiring insulin. The pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The t:slim X2 pump is indicated for use in individuals 6 years of age and greater. Control-IQ technology: Control-IQ technology is intended for use with a compatible integrated continuous glucose monitor (iCGM, sold separately) and ACE pump to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold. **Control-IQ technology is intended for the management of type 1 diabetes mellitus in persons six years of age and greater**.

**BOXED WARNING:** Control-IQ technology should not be used by anyone under the age of six years old. It should also not be used in patients who require less than 10 units of insulin per day or who weigh less than 55 pounds.

Control-IQ technology is not indicated for use in pregnant women, people on dialysis, or critically ill patients. Do not use Control-IQ technology if using hydroxyurea. Users of the t:slim X2 pump and Control-IQ technology must: use the insulin pump, CGM, and all other system components in accordance with their respective instructions for use; test blood glucose levels as recommended by their healthcare provider; demonstrate adequate carb-counting skills; maintain sufficient diabetes self-care skills; see healthcare provider(s) regularly; and have adequate vision and/or hearing to recognize all functions of the pump, including alerts, alarms, and reminders. The t:slim X2 pump, transmitter, and sensor must be removed before MRI, CT, or diathermy treatment. Visit tandemdiabetes.com/safetyinfo for additional important safety information.

**Insulin Pump Use and Diabetes**

Diabetes is a chronic, life-threatening disease that affects more than 30 million people in the United States, or nearly 1 in 10 Americans. Tandem estimates that more than three million people in the United States require daily administration of insulin and are candidates for pump therapy. More than 500,000 Americans with type 1 diabetes use an insulin pump, or approximately 30 percent of the type 1 diabetes population. In addition, approximately 100,000 Americans with type 2 diabetes use an insulin pump, which is less than 10 percent of the type 2 diabetes population using intensive insulin therapy management.

**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 with Control-IQ technology. The t:slim X2 pump is capable of remote feature updates using a personal computer, and is the only automated insulin dosing device approved for children as young as 6 years old. Tandem is based in San Diego, California.



---

1. As measured by CGM

2. Zero fingersticks required when using the t:slim X2 pump with Dexcom G6 CGM integration. If glucose alerts and CGM readings do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions. Dexcom G6 CGM sold separately. Dexcom transmitter can only be paired with one medical device (either a Dexcom receiver or t:slim X2 pump) and one consumer device (phone or tablet) at the same time.

3. Wadwa RP. Impact of Control-IQ on glycemic control for school age children with T1D. Industry Symposium. ATTD, Madrid, Spain; February 20, 2020. https://www.youtube.com/watch?v=Tb-2NIify90&feature=youtu.be

4. If glucose values are predicted to be above 180 mg/dL, Control-IQ technology calculates a correction bolus using the Personal Profile settings and a target of 110 mg/dL and delivers 60 percent of that value. It will do this up to once per hour as needed. An Automatic Correction Bolus will not occur within 60 minutes of a bolus that has been delivered or cancelled.

5. G6 readings can be used to make diabetes treatment decisions when taking up to a maximum acetaminophen dose of 1,000 mg every six hours. Taking a higher dose may affect the G6 readings.

6. Requires separate Dexcom Follow app.

7. 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.

# # #

**Tandem Diabetes Care Contact Information:**

Media: Steve Sabicer, 714-907-6264, ssabicer@thesabicergroup.com

Investors: Susan Morrison, 858-366-6900 x7005, IR@tandemdiabetes.com