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

Exhibit 99.1

FOR IMMEDIATE RELEASE

Tandem Diabetes Care Announces FDA Approval of t:slim X2 Insulin Pump with Basal-IQ Technology

New Predictive Low Glucose Suspend Feature to Launch with Dexcom G6 CGM System Integration

San Diego, CA – June 21, 2018 – 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 of 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). This is the first automated insulin delivery system approved for use by children as young as 6 years old, and the first insulin pump designated as compatible with integrated continuous glucose monitoring (iCGM) devices. The Company plans to launch its new product with Dexcom G6® continuous glucose monitoring (CGM) integration, which requires no fingersticks for calibration or diabetes treatment decisions and was the first CGM device to receive the iCGM designation from the FDA earlier this year.[1,2,3] Tandem expects the t:slim X2 Pump with Basal-IQ technology to be available in August 2018, and all in-warranty t:slim X2 users in the United States will have the option to add the new feature free of charge via remote software update.[4]

Tandem's Basal-IQ algorithm is designed to look 30 minutes into the future to predict where glucose levels are heading. The device suspends insulin delivery when low glucose is predicted, then automatically resumes insulin delivery once glucose levels begin to rise. Use of the t:slim X2 Pump with Basal-IQ technology in the pivotal clinical study demonstrated a 31 percent relative reduction in time spent below 70 mg/dL, with no rebound hyperglycemia compared to a CGM-enabled insulin pump without the feature.

"Hypoglycemia can be a significant source of fear for people who use insulin and is a major cause of hospitalizations for people with diabetes," said Dr. Greg Forlenza, Assistant Professor of Pediatrics at the Barbara Davis Center, and one of the principal investigators in the PROLOG (PLGS for Reduction of Low Glucose) trial. "Basal-IQ technology proved very effective in the clinical trial at reducing time spent in hypoglycemia and improving time in range. The system was also simple to learn and use, so the training burden was minimal for the clinics and study participants compared to other automated insulin delivery systems."

"The t:slim X2 Pump with Basal-IQ technology was designed to predict and help prevent time spent low using best-in-class CGM technology," said Kim Blickenstaff, president and CEO of Tandem Diabetes Care. "As the first company to launch a touchscreen insulin pump capable of remote feature updates, and now the first to have a pump approved with iCGM compatibility, we are delivering new innovation to our customers at a pace that is unprecedented in our industry, furthering our mission to help improve the lives of people with diabetes."

Benefits of the New Basal-IQ Predictive Low Glucose Suspend feature:

Predicts and helps prevent lows – Using CGM values, the Basal-IQ feature looks ahead 30 minutes and suspends insulin when glucose is predicted to drop below 80 mg/dL or if glucose is currently below 70 mg/dL and falling. The system resumes insulin once glucose values start to rise.

No fingersticks – With Dexcom G6 CGM integration, the Basal-IQ feature works with no fingersticks required for mealtime dosing or calibration.[1] 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 5 followers.[6]

Works silently in the background - No additional alerts or alarms are required to use Basal-IQ technology compared to standard CGM-enabled pumps. Users can choose whether or not to receive alerts when insulin is suspended and resumed based on their personal preference.

No complicated modes to manage – The Basal-IQ feature has no complicated settings to manage and operates without constant input or interaction. The user only has to decide whether they want the feature on or off.

Standard features of the t:slim X2 Insulin Pump:

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 Basal-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.

#1-rated customer support – Tandem's California-based customer support has consistently ranked number one by pump users in independent patient surveys since 2012.[8]

For additional 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

Free Demo App – Basal-IQ Technology Coming Soon
Tandem's free t:simulator™ App will be updated in early July to let you experience the touchscreen interface of the t:slim X2 Pump with Basal-IQ technology directly on your mobile device. For more information and to download the app, visit http://www.tandemdiabetes.com/tsimulator.

Free Software Update for Current t:slim X2 Pump Users
All in-warranty t:slim X2 Pump users in the United States have the option to add the Basal-IQ feature free of charge via a software update using a personal computer. The Basal-IQ feature update will require a user to secure a new prescription from his or her healthcare provider and complete a 45-minute online training module. Internet and computer access are required for pump updates. Tandem expects the Basal-IQ software update to be available for current t:slim X2 Pump users in August 2018. Information about the requirements and update process is available at www.tandemdiabetes.com/X2update.

Basal-IQ Technology – Clinical Outcomes
In February 2018, the Company reported results from the six-week PROLOG (PLGS for Reduction of Low Glucose) pivotal trial, a randomized crossover study comparing two three-week periods of at-home insulin pump use, one period using the t:slim X2 Pump with Basal-IQ technology, and another period using a standard CGM-integrated t:slim X2 Pump without automated insulin suspension. The study included 103 participants with type 1 diabetes age 6 to 72 at four research centers across the United States. Use of the system with Basal-IQ technology reduced the number of sensor glucose readings below 70 mg/dL by 31 percent compared to the control period using a standard CGM-integrated t:slim X2 Pump without automated insulin suspension. Importantly, this marked reduction of time spent in low glucose was accomplished without any increase in the rate of hyperglycemia and participants overwhelmingly described the system as simple to learn and use[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 three 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 percent 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.

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

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 relate to, among other things, the anticipated timing for the commercial launch of the t:slim X2 with Basal-IQ and our ability to offer the Basal-IQ software update for current t:slim X2 Pump users. These statements are subject to numerous risks and uncertainties, including our ability to commence commercial scale manufacturing of the t:slim X2 with Basal-IQ technology, our ability to launch a new system to facilitate online training and prescription handling for existing t:slim X2 customers upgrading their existing devices, and the risk that we may encounter other challenges that may delay the commercial launch of t:slim X2 with Basal-IQ, 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. 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] If glucose alerts and CGM readings do not match symptoms or expectations or if taking over the recommended maximum dosage amount of 1000mg of acetaminophen every 6 hours, use a blood glucose meter to make diabetes treatment decisions.
[2] Dexcom G6 CGM sold separately
[3] The Dexcom G6 CGM 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.
[4] A new prescription and additional training are required for this software update.
[5] Dexcom G6 CGM readings can be used to make diabetes treatment decisions when taking up to a maximum acetaminophen dose of 1,000mg every 6 hours. Taking a higher dose may affect the G6 readings.
[6] Separate Follow App required.
[7] 38 percent 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.
[8] dQ&A USA Diabetes Connections Surveys, 2013-2017
[9] Buckingham B, et al. PROLOG: A Randomized Clinical Trial to Assess The Efficacy of Predictive Low Glucose Suspend Versus Sensor-Augmented Pump Therapy in The Management of Type 1 Diabetes [Session #026]. Vienna, Austria: 11th Annual Advanced Technologies and Treatments for Diabetes Conference; 2018.